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Mitigation of Worker Exposure to Ethylene Oxide

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Gaseous ethylene oxide (ETO) is widely used to sterilize and fumigate a wide variety of goods which may be otherwise damaged by alternative treatment techniques. Workers engaged in ETO sterilization/fumigation procedures may be commonly exposed to ETO. Such exposure may be associated with adverse health consequences.

This report describes the equipment and treatment procedures in use at selected sites and identifies and categorizes situations leading to worker exposure to ETO. Existing engineering, workplace design, and work practice measures to control worker exposure are identified and categorized. The extent to which these measures have beem implemented is also presented. In addition, this report briefly describes techniques and equipment available for ambient ETO monitoring and identifies their advantages and limitations.

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Neal Zank

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Sponsor: U.S. Environmental Protection Agency
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ABSTRACT

Gaseous ethylene oxide (ETO) is widely used to sterilize and fumigate a wide variety of goods which may be otherwise damaged by alternative treatment techniques. Workers engaged in ETO sterilization/fumigation procedures may be commonly exposed to ETO. Such exposure may be associated with adverse health consequences.

This report describes the equipment and treatment procedures in use at selected sites and identifies and categorizes situations leading to worker exposure to ETO. Existing engineering, workplace design, and work practice measures to control worker exposure are identified and categorized. The extent to which these measures have been implemented is also presented. In addition, this report briefly describes techniques and equipment available for ambient ETO monitoring and identifies their advantages and limitations.

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FOREWORD

The United States Environmental Protection Agency (EPA) registers all pesticide formulations used in the United States under authority of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 135 et seq.). The continued registration of any pesticide is questioned if the compound presents environmental risks or exhibits characteristics which are potentially harmful to human health. In such a case the EPA may issue a notice of rebuttable presumption against registration (RPAR), which allows for a period of information gathering and public comment before a subsequent registration decision is made by the Administrator. A notice of RPAR of ethylene oxide (ETO) was issued in the Federal Register, Vol. 43, No. 19, on January 27, 1978 and was based upon the scientific data cited in that notice.

The Administrator's registration decision ultimately will take the form of unmodified continued registration, restricted registration, or cancellation of the EPA registrations of ETO. In arriving at this decision in any given case, the Administrator must consider the benefits obtained from present uses of ETO, the risks associated with exposure, and the economic impacts associated with restriction or cancellation of the pesticide registrations.

This report is intended to assist the Administrator by identifying events and sources of potential worker exposure to ETO and the engineering, workplace design, and work practice measures available to control such exposure. Included in this report are data depicting the effectiveness of available control measures and assessments of the extent to which such measures have been implemented at various sites of use. Also included are descriptions of sampling techniques and instruments available for measurement of ambient ETO concentrations.

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EXECUTIVE SUMMARY

The objective of this study is to identify and categorize engineering, workplace design, and work practice measures available to control worker exposure to ethylene oxide (ETO) in facilities where it is used as a sterilant/fumigant. Specifically, the equipment and procedures in use for ETO application at 12 sites are identified. Existing measures to control worker exposure to ETO are also identified. In addition, techniques and equipment available for monitoring ambient ETO concentrations are described.

ETO treatment is most commonly conducted in a vacuum chamber (a hermetically sealed, high pressure vessel equipped with a vacuum system). The vacuum system is used to evacuate air from the chamber prior to introduction of the sterilant and to remove a portion of the ETO/air mixture from the chamber at the conclusion of the treatment cycle. The exhausted mixture is typically vented to the outside atmosphere or, after being mixed with water, to a sewer drain. Vacuum chambers range in size from less than 4 cubic feet to 3000 cubic feet and are the most common type of equipment used at 10 of the 12 selected sites.

Monitoring equipment used to measure ambient ETO concentrations can be divided into two basic categories: personnel monitoring and area monitoring. Personnel monitoring equipment is used to determine actual levels of worker exposure and to verify compliance with applicable standards by providing an integrated exposure value (time weighted average). While readily portable, extremely sensitive, and specific to ETO, personnel monitoring techniques require laboratory analysis. The resulting data do not indicate the specific source or event associated with exposure and may mask short term exposure to high ETO concentrations.

Direct reading instruments, which provide immediate, quantitative indication of ambient ETO levels, are used for area monitoring. Such instruments are suitable for determining peak concentrations, and changes in concentrations over time and at different locations within the work area; however, their primary limitations are related to specificity and portability.

The most commonly used type of direct reading instrument is a portable infrared gas analyzer. Depending upon the wavelength used, Freon®, carbon dioxide, or water vapor may act as interfering substances. In addition, such instruments have been reported to have limited accuracy at low concentrations (less than 10 ppm) (Opp 1980). Other types of direct reading instruments employ combustion, thermal conductivity, flame ionization, photoionization, and colorimetric detection mechanisms.

Employees involved in the treatment process as well as others in the general vicinity may be exposed to gaseous ETO which is released to the workplace. Common sources of release prior to and during the cycle include leaks from gas delivery systems, leaks from door gaskets, and releases from chambers not designed to effect a hermetic seal. In addition, ETO may be released to the workplace during the exhaust phase of the vacuum cycle from spillage at the drain vent connection, leaks from the chamber vent system, and, in some instances, from chambers which are vented directly into the workplace.

The greatest opportunity for worker exposure occurs after completion of the cycle, when the chamber is opened and the treated goods are removed and transferred to an aerator or aeration area. When the door is opened, unevacuated gases remaining in the chamber rapidly escape and disperse throughout the workplace. In addition, workers may be exposed to ETO which offgasses from the treated goods during transfer and in storage as well as from aeration cabinets which are vented directly into the workplace. Finally, workers who are engaged in replacing emptied sterilant cylinders may be actively exposed to ETO which remains in the cylinder and in transport lines.

In addition to these common sources of release, other less frequent occurrences may result in worker exposure, including: failure of door locking mechanism, maintenance or repair work resulting from equipment breakdown or system malfunction, release of chamber pressure relief valve, and major ETO leaks from the tank, tank valves, or ruptured gas lines.

Available data indicate the average worker exposure levels comply with current standards (50 ppm as an 8 hour time weighted average exposure); however, many workers may be exposed to high ETO concentrations for short time periods.

Available control measures to mitigate worker exposure include engineering modifications to the sterilization/fumigation equipment as well as workplace design and work practice considerations. In general, engineering modifications address specific exposure sources by preventing or minimizing the release of ETO to the workplace. These encompass control systems to monitor leaks to the chamber, improvements in the effectiveness of the evacuation system, and internal or external ventilation systems, among others.

Leak detection and control systems are incorporated as standard features in some new chamber designs (AMSCO Eagle Series and 3M 400B and 202B models, among others) and are intended to notify the chamber operator or abort the cycle in the event of a leak. Such measures are, however, not available for retrofitting onto existing installations.

A number of improvements to the chamber evacuation system are currently available. Successive multiple post-vacuums are offered by AMSCO, Vernitron, and Beverly Pacific; pulsating post-vacuum modifications are offered by Castle-Sybron, and continuous purge evacuation systems are offered by 3M. The pulsating post-vacuum is associated with a 52 percent reduction in average ambient ETO concentrations during the first 5 minutes after door opening and an 86 percent reduction in operator exposure (Samuels and Corn 1979b). The continuous purge feature, which allows air to pass through the chamber until the door is opened, is associated with peak ETO release of approximately 6 ppm (Samuels and Corn 1980), a significant reduction from typical levels which may range from 100 to 1000 ppm (Ackert 1980).

Control features are also available to separate and divert ETO which may be released at the drain vent (liquid/gas separator) and to capture and remove ETO which escapes from the chamber after the sterilizer door is opened. External ventilation systems (exhaust hoods) are commercially available for some small units (3M, Castle-Sybron, H.W. Andersen). Use of such a hood was found to reduce peak ETO concentration from approximately 600 to 1200 ppm to approximately 60 to 70 ppm and to reduce operator exposure levels by approximately 52 to 63 percent (Samuels and Corn 1979a).

Internal ventilation systems incorporated into large industrial chambers are designed to create an airflow from the workplace through the chamber, to assure that little or no ETO is released to the workplace. Such systems may be implemented by modifying the chamber recirculation system, by operating the vacuum pump after the chamber door is opened, or by installing a separate exhaust system into the chamber roof.

Workplace design considerations include the provision of adequate ventilation, whether general area or local exhaust, and isolation of exposure sources by physical barriers or distance. General area ventilation primarily serves to dilute any ETO which is released to the workplace and thereby to control passive exposure. Local exhaust ventilation systems capture and remove ETO from a number of potential release sources by the appropriate location of vent ducts. Similarly, passive exposure can also be controlled by construction of partitions around the chamber machinery area, by centralizing and restricting access to sterilization facilities, and by traffic control within these areas.

Work practices also may be instituted. Specific operating procedures, reinforced by training, may serve to reduce unnecessary worker exposure. On occasion, use of protective clothing and respiratory equipment may be appropriate. Finally, preventive maintenance programs may control the release of ETO from leaks and other system malfunctions.

Many ETO-user facilities have incorporated some equipment, workplace design, and work practice features which serve to control unnecessary worker exposure. In many cases, these were included in the initial chamber installation rather than incorporated at some later date for the specific purpose of reducing worker exposure. In general, health care and industrial ETO users have been most likely to implement control measures, often in response to monitoring programs which identified specific high exposure events. ETO users at other sites have generally made little effort to assess and control worker exposure.

Based on available information, it was concluded that ETO exposure levels could be reduced substantially below current standards by the implementation of available control measures. Some industrial ETO users have lowered average worker exposure levels to 5 ppm as an 8 hour time weighted average. Other ETO users have implemented controls sufficient to comply with current standards but are delaying implementation of additional measures until the anticipated standard revisions are published in order to be assured that they will be in compliance.

1.0 INTRODUCTION

Gaseous ethylene oxide (ETO) is widely used as a sterilant for the treatment of a wide variety of heat and moisture sensitive items that would be otherwise damaged by steam sterilization. It is used to sterilize reusable items at hospitals and other health care and health diagnosis facilities and by industrial manufacturers to process packaged, presterilized, disposable medical items. Because it is effective at ambient temperature and humidity, it is also used to decontaminate a wide variety of non-medical items, including spices and food packaging, books, archival materials, museum artifacts, laboratory apparatus, and beehives, among others.

Workers engaged in the ETO treatment processes, as well as other workers present in the general vicinity, may be routinely exposed to ETO. Such continuous occupational exposure is considered to be a potential health hazard to these workers. The National Institute for Occupational Safety and Health (NIOSH) recommends that ETO be considered mutagenic and potentially carcinogenic to humans and that occupational exposure be minimized through the implementation of various control measures, such as improved equipment design, workplace design, and work practices (Glaser 1977).

1.1 Scope

This report identifies the control measures which are currently available to users of ETO and assesses the extent to which these measures have been implemented at various sites of use. The sites of use considered are:

- Health care and health diagnosis and treatment facilities
- Medical products industry
- Libraries
- Museums
- Research laboratories
- Transportation sites
- Beekeeping industry
- High containment agricultural research laboratories
- Animal and plant health service quarantine at ports of entry
- Spices, seasonings, and black walnut meats industry
- Cosmetics industry
- Dairy packaging industry.

Specifically, the types of sterilization/fumigation equipment and procedures used at each of the above sites are identified and categorized. Situations resulting in potential worker exposure are identified and categorized according to the causal factors, the likelihood of occurence, and the extent of ETO release.

Sampling techniques and instruments capable of measuring ambient ETO are identified and assessed in terms of range, specificity, intended use and ease of operation.

In addition, engineering, workplace design, and work practice modifications available to minimize worker exposure are identified.

These control measures are compared with the situations resulting in ETO release/exposure to assess possible gaps or alternative approaches in mitigating worker exposure. Available data regarding the extent of exposure reduction associated with specific control measures are presented.

For each site of use, information is presented for individual facilities that summarizes the equipment in use, the nature of actual or potential exposure situations, and the types of control measures which have been implemented to mitigate worker exposure.

1.2 Approach

This report utilizes information derived from the existing literature, unpublished reports, and personal communications.

An extensive computerized data search was conducted to identify relevant literature related to use and worker exposure to ethylene oxide in industries where it is used as a sterilant/fumigant. Articles related to exposure levels, routes of exposure, instances of exposure, and methods of mitigating worker exposure were searched. The following data bases were accessed:

- Medline and backfiles - 1966 to present
- Health Planning and Administration - 1975 to present
- Toxline and Toxback*

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*Toxline and Toxback contain a variety of files, most of which begin between 1965 and 1970.

In addition to direct contact of ETO users, trade associations whose members use ETO for sterilization or fumigation were contacted and their cooperation elicited in gathering information from their members regarding the types and effectiveness of control measures that have been implemented at individual facilities. These trade associations and the number of member companies from which information was requested are:

- American Hospital Association - 200 hospital central supply departments
- Health Industry Manufacturers Association - 130 member companies
- American Spice Trade Association - 27 member companies

Finally, site visits were also made in the course of this study (see Appendix A).

1.3 Limitations of Study

As published information regarding the nature and extent of worker exposure to ETO and available measures to control such exposure is limited, primary sources were relied upon. Many of these sources, primarily industrial users of ETO, however, were reluctant to provide monitoring data as such information was generally considered to be proprietary.

Much of the collected information regarding worker exposure to ETO pertains to the use of ETO at hospital facilities. Such information may not be directly applicable to other user sites due to differences in equipment, procedures, and the nature of the goods being processed.

Information on the available control measures for mitigating worker exposure to ETO was obtained primarily from manufacturers of sterilization/fumigation equipment. As such, the information may not be exhaustive as ongoing modifications and control technologies being developed by individual facilities may not have been identified. Data regarding the effectiveness of these modifications are extremely scarce. Most of the efforts to assess the effectiveness of control measures have been limited to specific engineering controls; little evaluation has been conducted of workplace design or work practice measures and no information was identified to assess the marginal reduction in worker exposure associated with a combination of control measures. Consequently, it was not possible to provide estimates of the extent of reduction in worker exposure associated with many workplace or work practice control measures. In addition, the available data may not be representative of the effective reduction of exposure at facilities other than those where the evaluation was conducted; differences in the equipment, goods treated, workplace design, and operating practices employed at user sites limit such generalization.

Assessment of the extent to which control measures have been implemented is based on a limited sample of the total user population at each site of interest. The information at three sites (hospitals, medical products industry, and spice trade industry) was collected by their respective trade associations. Because of the decision of these associations not to identify the facilities providing the information, it was not possible to verify or supplement any of the reported information. In addition, it was not possible to identify health diagnosis facilities (doctors, dentists, and veterinarians in private or clinical practices) who may be using ETO sterilization equipment. Medical, dental, and veterinary professional associations who were contacted in the course of this study were unable to provide any information regarding ETO use among their members.

2.0 STERILIZATION/FUMIGATION EQUIPMENT AND PROCEDURES

Sterilization/fumigation with ETO is accomplished by exposing the contaminated materials to gaseous ETO for an extended period of time. The treatment process is conducted in a closed system to facilitate maintenance of the required gas concentration over the exposure period.

Various types of containment equipment are used for ETO sterilization/fumigation. The types of equipment may be categorized as follows:

- Chambers
  - vacuum
  - atmospheric
- Other containment equipment
  - ampule/liner bag
  - single item sterilizer (Sterijet®)
  - tarpaulin

In some instances no separate containment equipment is used. Rather, the item being treated itself serves as the enclosure. Table 2-1 summarizes the types of equipment used at the selected sites. The equipment and associated procedures are discussed below and presented in more detail in Section 6.0.

2.1 Chambers

2.1.1 Vacuum Chambers

Vacuum chambers are the most commonly used type of ETO sterilization/fumigation equipment. These chambers are basically

TABLE 2-1

TYPES OF ETO STERILIZATION/FUMIGATION
EQUIPMENT USED AT DIFFERENT SITES

Equipment Sites of Use	Vacuum Chamber	Atmospheric Chamber	Ampule/Liner Bag	Sterijet System	Tent Fumigation	No Containment
Health Care and Health Diagnosis and Treatment Facilities	✓	✓	✓	✓		
Medical Products Industry	✓			✓		
Libraries	✓					
Museums	✓	✓				
Research Laboratories	✓					
Transportation Sites						✓
Beekeeping Industry	✓	✓				
High Containment Research Laboratories in Agriculture	✓					
Animal and Plant Service Quarantine at Ports of Entry					✓	
Spices, Seasonings, and Black Walnut Meats Industry	✓					
Cosmetics Industry	✓					
Dairy Packaging Industry	✓					

pressure vessels equipped with a vacuum system which operates intermittently during the treatment process. The vacuum pump is used to remove air from the chamber at the beginning of the treatment process in order to facilitate diffusion of ETO into the contaminated material and again after the exposure period to remove some of the ETO/air mixture present in the chamber. Typically, the evacuated ETO is vented either to the outside atmosphere or to the sewer.

2.1.1.1 Equipment. Vacuum chambers may be categorized by size into small (less than 4 cubic feet), intermediate (greater than 4 cubic feet and less than 100 cubic feet) and large (greater than 100 cubic feet) chambers.

Small chambers are primarily countertop models and are most commonly used in health care and health diagnosis facilities. In hospitals, they are primarily located in decentralized sterilization facilities such as inhalation therapy centers and operating rooms (Ackert 1980; Mack 1980). Such chambers are also used to a limited extent in research and industrial facilities.*

Manufacturers of such chambers identified in the course of this study include Advanced Instruments, Amdek, American Cystoscope Maker (ACMI), The 3M Company (3M), American Sterilizer Company (AMSCO), and Vernitron. Only the last three companies continue to market such chambers.

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*Examples of industrial users of small chambers include manufacturers of contact and interoccular lenses (Ackert 1980).

Small vacuum chambers utilize either unit dose cartridges containing a premeasured amount of 100 percent ETO (Advanced Instruments, Amdek, ACMI and 3M) or a gas mixture of 12 percent ETO/88 percent Freon® in pressurized cylinders (AMSCO, Vernitron). Chambers designed to utilize unit dose cartridges are equipped with a receptacle into which the cartridge is placed. The sterilant is released by puncturing the cartridge either manually, by screwing down a cap over the receptacle, or automatically, as in the newer 3M models. AMSCO and Vernitron chambers incorporate an external gas delivery system. The cylinders are connected to the sterilizer by means of valves, fittings, and piping.

Small chambers are generally vented directly to the outside atmosphere via a length of copper or plastic tubing. Some earlier models, primarily those intended to be portable, were vented either directly into the workplace or into a sponge kept damp in a bucket of water.*

Intermediate-sized chambers are used primarily in hospital central supply facilities. Other use sites include research and industrial facilities, libraries, museums, and beehive fumigation facilities. Manufacturers of such chambers include AMSCO, Castle-Sybron, Miskoe, Vacudyne-Altair and Vernitron. AMSCO, Castle-Sybron, and Vernitron primarily market to hospital users, although they also sell their chambers to research and industrial facilities. Vacudyne-Altair and Miskoe manufacture fumigators; the former markets to libraries, archives, and museums and the chambers manufactured by Miskoe are used exclusively for beehive fumigation.

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*Venting into a damp sponge had been, at one time, recommended as an alternative to a fixed vent line to the atmosphere by Advanced Instruments, Amdek, and ACMI (Emergency Care Research Institute (ECRI) 1975). No information was available to estimate the number of small vacuum chambers which may still be vented in this manner.

Intermediate-sized chambers are available in various configurations. Vacudyne-Altair and Miskoe units are typically freestanding while AMSCO, Castle-Sybron, and Vernitron chambers may be freestanding or, as in many hospital installations, built-in. The latter are available in single or double door designs. Double door chambers are used in some hospital central supply departments and high containment research laboratories to permit loading the unsterilized goods from a contaminated area and unloading them, after processing, into a "clean" area.

All the intermediate-sized chambers identified in the course of this study utilize gas mixtures in pressurized cylinders. Some of the newer models manufactured by AMSCO, Castle-Sybron, and Vernitron are designed to permit several cylinders to be connected to the sterilizer, thereby minimizing the possibility that a cycle will be aborted due to insufficient sterilant supply.

These chambers are vented either directly to the outside atmosphere (Vacudyne-Altair, Miskoe)* or to a sewer drain (AMSCO,

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*Miskoe chambers are frequently located outdoors. Some of these chambers are equipped with a long vent line to direct the exhausted gases to an area some distance from the chamber (see Section 6.7).

Castle-Sybron, Vernitron). In the latter installations, the exhausted gases are directed through the water ring seal component of the vacuum pump where they are mixed with the water. The liquid/gas mixture is then directed to a floor drain typically located near the rear of the chamber.*

Large chambers may range from 100 cubic feet upwards to 3000 cubic feet and are used primarily for the industrial sterilization of medical products, spices and other commodities. These chambers are custom manufactured by AMSCO, Vacudyne-Altair, Environmental Tectonics, Beverly Pacific, and Vernitron to meet the specifications of the user.

Approximately 1000 such chambers are estimated to be in use (Nusbaum 1980b). Of these, approximately 250 to 275 have been manufactured by Vacudyne-Altair (Markinson 1980a), 100 by Environmental Tectonics (D'Aquila 1980), 60 to 70 by Beverly Pacific (Sias 1980), and 300 to 350 by AMSCO (Spoden 1980).

Industrial chambers may utilize 100 percent ETO** or a gas mixture. Some chambers are designed to permit use of either sterilant formulation. Sterilant formulations are supplied in pressurized cylinders or, in some cases, in large tanks (Skocypec 1980). Most typically, exhausted gases from large industrial chambers are vented, after being mixed with water, to a sewer drain.

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*Local plumbing codes frequently preclude a solid connection between the vent line and the sewer drain in order to prevent the possible back-up of sewer gases.

**Cycles which utilize 100 percent ETO operate under negative pressure throughout the exposure phase.

2.1.1.2 Procedure. While vacuum chambers vary widely in size and design features, they entail essentially the same operating sequence as follows:

- Contaminated material is loaded into the chamber.
- The chamber door is closed to effect a hermetic seal
- A vacuum is created in the chamber (pre-vacuum) to remove air which acts as a barrier to the diffusion of heat, moisture, and ETO into the load.
- ETO is vaporized and introduced into the chamber to a predetermined pressure or concentration. The sterilant may be either 100 percent ETO or a nonflammable mixture of either 12 percent ETO/88 percent Freon® or, less commonly, 10 percent ETO/90 percent carbon dioxide.
- The load is exposed to gaseous ETO for a predetermined period. When 100 percent ETO is used, a sub-atmospheric pressure is maintained throughout the exposure phase (Ackert 1980; Markinson 1980b). Cycles using gas mixtures operate under positive pressure during the gas exposure phase.
- A vacuum is created in the chamber to remove ETO (post-vacuum or exhaust vacuum). The ETO/gas mixture is vented from the chamber and directed, via a vent line, to the outside atmosphere or to a sewer drain.
- Filtered air is introduced into the chamber until atmospheric pressure is reached.
- The chamber is opened and the treated materials are removed. They may, at this point, be transferred to an aeration cabinet* or placed in a storage area.

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*Aeration cabinets circulate air at elevated temperature around the treated goods to facilitate offgassing of residual ETO which may be absorbed or entrapped in these goods. Aeration cabinets are used almost exclusively in hospital sterilization facilities. Aeration cabinet venting is discussed in Section 5.1.6.3.

The procedures followed in unloading the chamber and handling the treated goods vary both with the chamber size and the type of facility. In general, small vacuum chambers are unloaded manually (i.e. one item at a time). Some of these chambers are equipped with metal baskets to minimize the necessity for direct handling of treated goods and to minimize the time required to unload the chamber and transfer its contents. Many intermediate-sized chambers, particularly those used in hospital central supply departments, utilize multi-tiered carts which are designed to fit into the chamber and then to be transferred directly to a compatibly sized aeration cabinet.

Large industrial chambers often require the operator to enter the chamber to remove the treated goods. In some facilities, chambers are equipped with a roller mechanism which permits pallets to be brought to the front of the chamber and eliminates the need for the operator to enter the chamber (see Sections 6.2 and 6.10). Typically, these goods are transported by hand trucks or fork lift trucks to a storage area.

2.1.2 Atmospheric Chambers

Atmospheric chambers do not utilize a vacuum pump to evacuate the chamber. Because an initial vacuum is not created to eliminate the barrier action of the air present in the chamber, longer exposure times are typically necessary.

The design features and operating procedures of atmospheric chambers identified in the course of this study vary widely. Four manufacturers of such chambers have been identified. Ben Venue and Castle-Sybron manufacture small chambers which are used primarily in health care and health diagnosis facilities.* These chambers are unvented and utilize unit dose cartridges containing gas mixtures. In both cases, as the vaporized ETO enters the chamber, it displaces air which is directed out the top of the chamber. In the Ben Venue chambers, a charcoal absorbant is incorporated into the chamber top to capture escaping ETO. No absorbant or other diversionary device is incorporated into the relief valve of the Castle chamber.

At the completion of the exposure period, the Ben Venue chambers utilize a manual pumping action (repeated lifting and lowering of the outer chamber) to force air into the chamber and direct the ETO through the charcoal absorbant. No venting mechanism or system is incorporated in the Castle 1500 atmospheric chamber.

AMSCO manufactures industrial chambers which are designed for the treatment of goods packaged in hermetically sealed plastic wraps, as such packaging may otherwise be damaged by the vacuum/pressure changes of a typical cycle.* The treated goods are exposed to gaseous ETO under pressure. After completion of the exposure period, air, under pressure, is introduced into the chamber as the sterilant is being exhausted. This is repeated in timed intervals and the exhausted gases are vented to the outside atmosphere (Gunther 1980).

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*Approximately 4000 Ben Venue sterilizers have been sold since introduction in the mid 1950s. Of these, approximately 70 percent were sold to physicians in private practice, 10 percent to podiatrists, 2 to 3 percent to clinics and approximately 1 percent to veterinarians (Morgan 1980). Approximately 300 to 350 Castle Model 1500 chambers have been sold, primarily to hospitals (Frechette 1980).

The Kewaunee chambers are used for fumigation of museum artifacts. They utilize pressurized cylinders of ETO gas mixtures and are mechanically vented to the outside atmosphere (Canellos 1980).

2.2 Other Containment Equipment

2.2.1 Ampule/Liner Bag System

The H.W. Andersen Company markets an ETO sterilization system consisting of a nongasketed metal container, plastic liner bags, and glass ampules containing a unit dose of 100 percent ETO. These systems have been marketed for approximately 15 years.** They are available in three configurations: a cylinder and tray, each with approximately 0.3 cubic foot capacity, and a 2 cubic foot cabinet.

To operate this system, a new liner bag is spread out in the container. The goods to be treated are placed in the liner bag along with an ampule which has been broken along a prescored section. The liner bag is then closed with a twist-tie and the container is closed and locked with a key. The container and its contents are left undisturbed for 12 hours after which the container is unlocked and the materials removed (H.W. Andersen Products undated a).

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*Approximately 100 to 150 such chambers have been manufactured (Spoden 1980).

**Approximately 10,000 units have been sold over that period and approximately 15 million cycles have been operated over that time (Hamlin 1980a,b).

This sterilization system is not designed to retain the vaporized ETO. The liner bag is intended to serve as a diffusion membrane, retaining the ETO for a period sufficient to sterilize the contents and then enabling the ETO to escape slowly into the container and subsequently into the surrounding air. The non-gasketed container is primarily intended to serve as a guard against inadvertent ignition of the contents by a spark or open flame during the treatment process. Because ETO is designed to slowly escape from the Amprolene containers, the manufacturer recommends that the container be placed in a well-ventilated area (H.W. Andersen Products undated a).

2.2.2 Single Item Sterilization System (Sterijet®)

The Sterijet® system, manufactured by H.W. Andersen Products, is designed to sterilize individual items packaged in sealed pouches. This system is marketed to hospitals and industrial users, and consists of a machine to deliver a premeasured quantity of sterilant, plastic pouches in several sizes, and an aeration cabinet.

The operating sequence involves the following steps. The item to be sterilized is placed in an appropriately-sized pouch. The open ends of the pouch are then placed around a nozzle which protrudes between the two sealer pads of the gas delivery machine. The machine is activated by depressing a foot pedal which closes the sealer pads around the package edges and the protruding nozzle. A slight vacuum is drawn in the pouch and a premeasured quantity of sterilant is injected; the quantity is dependent upon the size of the pouch being used. After the sterilant is injected, the nozzle is automatically withdrawn and the package is heat sealed. The sealed package is then placed directly into an aeration cabinet or in a temperature-controlled aeration room where both sterilization and aeration take place. Sterilization is completed in 12 hours at elevated temperature (122°F) and aeration is completed after an additional 36 hours.

The pouch is designed to retain the ETO for a period sufficient to assure sterilization. During the sterilization period, ETO slowly eludes from the pouch so that at the conclusion of 12 hours the package has a vacuum-tight appearance. The vacuum tight appearance, designed to provide assurance of package integrity, is maintained until the package is opened for use or until the pouch is inadvertently pierced (Andersen 1980).

2.2.3 Tarpaulin Fumigation

Large tarpaulins, composed of gas impervious material,* may serve as temporary enclosures to contain the gaseous fumigant. Such containment systems are used almost exclusively at ports of entry for the fumigation of cargo infested with snails or certain plant disease organisms. Available information does not indicate that ETO tarpaulin fumigation is conducted at any other site of use.

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*Tarpaulins may be vinyl, rubber coated nylon, or polyethylene.

Equipment and procedures used in tarpaulin fumigation are specified in the U.S. Department of Agriculture (USDA) Plant Protection and Quarantine Programs Treatment Manual (1976).* Treatment is conducted by commercial fumigators and supervised by USDA inspectors.

The equipment used in tarpaulin fumigation consists of a tarpaulin without visible holes or tears, sand snakes or other means of sealing the edges of the tarpaulin,** a gas sampling and monitoring system, and the sterilant supply and delivery system. Fans to circulate the sterilant mixture and to aid in its removal are occasionally used. The sterilant formulation used is a mixture of 10 percent ETO/90 percent carbon dioxide.

The fumigation procedure is conducted away from normal work areas, either outdoors or in large buildings such as hangars or maintenance garages. The material to be treated is placed on an impervious surface and a wooden frame or other support system is constructed around it. The frame is designed to keep the tarpaulin 2 feet above the load to facilitate proper gas circulation. Fans to assist gas circulation, the sterilant supply line, and gas sampling lines are then positioned within the load. Any protrusions which may penetrate through the tarpaulin are cushioned with burlap and the tarpaulin hung loosely over the frame. The perimeter of the tarpaulin is then sealed with sand snakes, loose wet sand, or mastic sealer. Corners are frequently sealed with double sand snakes.

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*Sections III, parts 1 and 4 and Section IV parts T402 and T403 are applicable to ETO fumigation.

**Sand snakes are sleeves or tapes of canvas or heavy-gauge polyethylene filled with sand.

After inspection to verify the integrity of the enclosure, the fumigant mixture is introduced. If the entire cylinder is to be used it may be placed within the enclosure and the valve opened through the slack of the tarpaulin.

During the exposure period the gas concentrations within the enclosure are sampled at intervals to verify adequate concentration and dispersion. If there is evidence of a leak, a thermal conductivity analyzer or colorimetric gas detector tubes (see Section 3.0) are used to locate the source, which is then sealed.

At the conclusion of the fumigation period, the sterilant is vented from the enclosure by means of fans. These may be suction fans connected to large ducts which lead out from the tarpaulin or the fans used to circulate the ETO during exposure. When the latter are used, operators wearing respirators first cut or loosen the tarpaulin seal. After the enclosure is evacuated, verified by measurements taken from the sample lines extending from the enclosure, the operators return to remove the tarpaulin. Some fumigators then wait an additional 30 minutes to 3 hours before returning to the site for final clean up.

2.3 No Containment Equipment

Fumigation with ETO may also be accomplished in circumstances in which no separate containment equipment is used. In these instances the object being treated also serves as the containment equipment. This treatment technique is primarily applicable to the fumigation of seriously infested railroad cars.*

A standard procedure is followed in the fumigation of railroad cars. Cars to be fumigated are moved to a separate track and a contract exterminator is employed for the task. All food and food related items are removed and all openings other than an exit door are sealed with gum tape. A cylinder containing a mixture of 10 percent ETO/90 percent carbon dioxide is placed in the car. The valve is opened, the operator exits, and the door is sealed. Signs are placed around the car which indicate that fumigation is in process. After the exposure period, which lasts approximately 6 hours, the tape is removed, doors are opened, and the car is permitted to air for a period of approximately 2 hours. Operators wear respiratory equipment during periods of possible exposure to the fumigant (McKenzie 1979).

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*One instance of ETO fumigation of an entire library building was reported by Griffith (1979) in MITRE document Preliminary Benefits Analysis of Ethylene Oxide as a Fumigant in Libraries (Goldgraben 1980).

2.4 Summary

Table 2-2 summarizes information regarding commercially available ETO sterilization/fumigation equipment. For each manufacturer of such equipment, information is presented regarding chamber size, sterilant formulation used, sterilant delivery system, chamber venting system, and other features related to worker exposure. In addition, the primary markets are identified as well as estimates of the units sold or currently in use. Where several markets are noted, these are arranged in order of importance.

TABLE 2-2

SUMMARY OF ETO STERILIZATION/FUMIGATION EQUIPMENT

Type of Equipment	Manufacturer	Model	Size (ft^3)	Sterilant Formulation	Sterilant Delivery System	Chamber Venting	Features Relative to Worker Exposure	Comments	Site and Extent of Use	Reference
Vacuum Chambers	Advanced Instruments Inc. Needham, Heights, MA.	G1 G2 - Mark III G2 - Mark IV	1 2 4	100% ETO	Cartridge	Chamber vented to atmosphere or (optionally) into damp sponge[a].	Door cannot be opened during cycle due to vacuum.	No longer markets sterilizers; services existing chambers.	Hospital Inhalation Therapy Centers	ECRI 1975; ECON 1980
	Amsik Corporation Hudson, MA.	Steridome	2	100% ETO	Cartridge	Chamber vented to atmosphere or (optionally) into damp sponge[a].	Door cannot be opened during cycle due to vacuum.	No longer markets sterilizers; services and upgrades existing chambers by installation of improved seals and door gaskets and by installation of air wash cycle.	Hospitals Inhalation Therapy Centers Central Supply (approximately 150 units are currently in use)	ECRI 1975; Melonson 1980
	American Cystoscope Makers, Inc. (ACMI) Stamford, CT.	GS 10	2	100% ETO	Cartridge	Chamber vented to atmosphere or (optionally) into damp sponge[a].	Door lock.	No longer markets sterilizers; service and parts are unavailable.	Hospitals Physicians in private practice	ECRI 1975; Spucci 1980
	American Sterilizer Corp. (AMSCO) Erie, PA.	Portagas	2	12% ETO/ 88% Freon®	Cylinder	Optional vent to atmosphere.	-	-	Hospitals	ECRI 1975; AMSCO 1980
		Eagle 2025 Eagle 2035 Eagle 2045 Eagle 2055	8.8 18 24 30	12% ETO/ 88% Freon®	Cylinder	Vent to drain.	Automatic leak monitoring system. Multiple post-vacuum exhaust. Metal carts or wire racks available as options. Automatic door(s) available as option.	Current series introduced in February 1979.	Hospital Central Supply Research Laboratories (approximately 3600 chambers in use)	AMSCO 1979; Spoden 1980
		Medallion Series	N.I.	12% ETO/ 88% Freon®	Cylinder	Vent to drain.	Two post-vacuums standard feature.	Marketed from 1965 to 1979.	Hospitals Research Laboratories	Spoden 1980
		Cryotherm Series	N.I.	12% ETO/ 88% Freon®	Cylinder	Vent to drain.	N.I.	-	Hospitals Research Laboratories	Spoden 1980
		Industrial	up to 1100	12% ETO/ 88% Freon®	Cylinder	Vent to drain.	Same as standard sized units.	-	Industrial facilities (approximately 300-350 chambers)	Chamberlain 1980 Spoden 1980
	Beverly Pacific Corp. Burbank, CA.	N.A.	100 to 1500	100% ETO 12% ETO/ 88% Freon® 10% ETO/ 90% CO_2[b]	Cylinder	Vent to drain.	Dependent upon customer specifications.	-	Pharmaceuticals Medical Products Food Products (approximately 60-70 chambers have been sold).	Sias 1980

TABLE 2-2 (CONTINUED)

Type of Equipment	Manufacturer	Model	Size (ft^3)	Sterilant Formulation	Sterilant Delivery System	Chamber Venting	Features Relative to Worker Exposure	Comments	Site and Extent of Use	Reference
Vacuum Chambers (continued)	Castle-Sybron Corp. Rochester, NY.	3040; 3045; 3145 3240; 3260 4040; 4060	8.8 24 or 30 39 or 71	12% ETO/ 88% Freon®	Cylinder	Vent to drain.	Modified evacuation system (pulsating post-vaccum) available as option in new chamber and retrofit in existing chambers. Liquid-gas separator available as option for installation into vent line.	-	Hospital Central Supply Industrial Research Laboratories (approximately 2500 chambers have been sold, primarily to hospitals).	Frechette 1980; Weidrich 1980
	Environmental Tectonics Corp. Southampton, PA.	Industrial	200-1000	100% ETO 12% ETO/ 88% Freon®	Cylinder	Vent to drain.	Dependent upon customer specification.	-	Medical Products Pharmaceuticals Foods Products (approximately 100 chambers have been sold)	D'Aquila 1980
	Miskoe Engineering Concord, NH.	N.A.	49	10% ETO/ 90% CO 12% ETO/ 88% Freon®	Cylinder	Vent to atmosphere.	-	Miskoe chambers are typically located outdoors.	Beehive Fumigation	Miskoe 1980
	3M Corporation St. Paul, MN.	100 200	1 2	100% ETO	Cartridge	Vent to atmosphere.	External cartridge well. Operates under negative pressure throughout cycle.	Manufactured by Amdek for 3M (1967-1971); ceased sale of reconditioned units in 1974.	Hospitals Inhalation Therapy Centers Operating Rooms Industrial contact lens manufacturers interoccular lens manufacturers (approximately 3000 chambers have been sold).	Ackert 1980
		202 400	2 4	100% ETO	Cartridge	Vent to atmosphere.	Automatic cartridge puncture. Latter units include modified evacuation system (continuous purge). Door lock. Operates under negative pressure throughout cycle.	Model 400 introduced in 1969. Model 202 introduced in 1974. Continuously modified until 1978 when this series was discontinued.		Ackert 1980
		202B 400B	2 4	100% ETO	Cartridge	Vent to atmosphere.	Heated air wash (continuous purge) evacuation cycle. Automatic abort due to insufficient initial vacuum; leak to chamber, door not properly sealed.	Introduced in 1978.		Ackert 1980 Mach 1980

TABLE 2-2 (CONTINUED)

Type of Equipment	Manufacturer	Model	Size (ft^3)	Sterilant Formulation	Sterilant Delivery System	Chamber Venting	Features Relative to Worker Exposure	Comments	Site and Extent of Use	Reference
Vacuum Chambers (concluded)	Vacudyne Altair Chicago Heights, IL.	Vacufume - 18 Vacufume - 36 VFS - 100	18 36 100	12% ETO/ 88% Freon®	Cylinder	Vent to atmosphere or drain.	Operates under negative pressure throughout cycle.	-	Libraries Archives Museums (approximately 30-60 chambers have been sold)	Markinson 1979
		Industrial	100-1500	100% ETO/ 12% ETO/ 88% Freon®^{b}	Cylinder	Vent to drain.	Dependent upon customer specifications.	-	Medical Products Pharmaceuticals (approximately 250-275 chambers have been sold)	Markinson 1980
	Vernitron-Better Built Carlstadt, NJ.	Standard	4 9 18 24 30	12% ETO/ 88% Freon®	Cylinder	Vent to drain.	-	-	Hospitals Research Laboratories	Edick 1980 Kreyling 1980
		Custom	39 70 167 196	12% ETO/ 88% Freon®	Cylinder	Vent to drain.	Muliple post-vacuums.	-	Industrial	Edick 1980 Kreyling 1980
Atmosphere Chambers	American Sterilizer Corp. (AMSCO) Erie, PA.	Industrial	up to 1100	12% ETO/ 88% Freon®	Cylinder	Vented to atmosphere.	Compressed air introduced during evacuation stages.	Balanced pressure cycle used to preserve packaging integrity.	Industrial (approximately 100-150 chambers have been sold)	Gunther 1980 Spoden 1980
	Ben Venue Laboratories Inc. Bedford, OH.	N.A.	0.04	20% ETO/ 80% Freon®	Cartridge	Unvented.	Charcoal absorbent designed to capture escaping ETO. Manually operated.	Introduced in 1956.	Physicians in private practice	Morgan 1980
	Castle-Sybron Corp. Rochester, NY.	1500	1.3	12% ETO/ 88% Freon®	Cartridge	Unvented.	Door may be opened during cycle.	-	Hospitals (approximately 300-350 chambers have been sold)	ECRI 1975 Frechette 1980
	Kewaunee Scientific Equipment Corp. Adrian, MI.	N.A.	100-196	10% ETO/ 90% CO_2 12% ETO/ 88% Freon®	Cylinder	Vented to atmosphere.	-	-	Museums	Canellas 1980
Other Containment Equipment	H. W. Andersen Products Oyster Bay, NY.	AN 70 AN 72 AN 74	0.3 0.3 2	100% ETO	Glass ampule	Unvented.	Non-gasketed container.	-	Hospitals Laboratories Clinics Physicians in private practice (approximately 10,000 units have been sold)	H. W. Andersen Products undated Hamlin 1980b
		Steriljet®	N.A.	12% ETO/ 88% Freon 11	Automatic delivery system directly into plastic pouch.	Pouches placed in aerator during sterilization and aeration period.	Gas delivery system equipped with exhaust vent.	Single item sterilization system.	Hospitals Industrial	H.W. Andersen Products 1980a

TABLE 2-2 (CONCLUDED)

N.A. - Not applicable.
N.I. - No information available.

[a] Original recommendation offered by manufacturer; may no longer be observed by users.
[b] Dependent upon customer specifications.

3.0 ENVIRONMENTAL ETO MONITORING

Measurement of ambient ETO concentrations may be conducted for various purposes:

- To determine actual levels to which workers are exposed
- To determine if applicable exposure standards are being met
- To evaluate the work environment by locating release sources and potentially high exposure events
- To verify the performance of control equipment or measures
- To alert workers in the event that ambient concentrations exceed predetermined levels

The choice of monitoring equipment is dependent upon the purpose of the measurement. Equipment and techniques used to monitor ambient ETO concentrations may be classified into two categories: personnel monitoring and area monitoring.

3.1 Personnel Monitoring

Personnel monitoring techniques are used to determine the actual levels of ambient ETO to which workers are exposed and to verify compliance with applicable ETO exposure standards. Such techniques entail the use of a collection device which is affixed to the worker and worn throughout the workshift or for a specified period of time. The collected samples are then analyzed in a laboratory to determine an integrated value of exposure over the sample period. This value represents a time weighted average (TWA) exposure.*

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*The current U.S. Occupational Safety and Health Administration (OSHA) 8 hour TWA for occupational exposure to ETO is 50 ppm.

Three basic types of collection devices may be used to determine worker exposure to ETO: (1) sorbent tube containing activated charcoal, (2) gas bubble tube containing a liquid medium, and (3) sample bag. Specific information regarding these techniques, including analytical methods and the advantages and disadvantages associated with each, are summarized in Table 3-1.

The sorbent tube collection method is most commonly used to measure personnel exposure to ETO. The sorbent tube(s) containing activated charcoal are affixed to the worker near his breathing zone and connected via tubing to a small battery-operated pump worn at the waist. The pump draws a known volume of air through the tube and the ETO present in the air sample is adsorbed by the charcoal. After conclusion of the sample period, the tube is removed, capped, and sent to a laboratory for analysis. The analytical method entails desorption of the ETO, either with carbon disulfide or thermally, and subsequent gas chromatographic determination.

Three variations of the charcoal tube method are currently in use. These variations are primarily associated with the actual configuration and dimensions of the sorbent tubes (Table 3-1).

Impingers (gas bubble tubes containing a liquid medium) may be used. These are affixed to the worker in a manner similar to the attachment of charcoal tubes. Essentially, such collection devices convert the ETO in the air sample to ethylene glycol (ETG) in a dilute sulfuric acid medium followed by neutralization with 50 percent

TABLE 3-1

SUMMARY OF ETO PERSONAL MONITORING TECHNIQUES

Sample Collection Method	Analytical Method	Comments	Reference
Sorbent Tube Using Actived Charcoal - NIOSH Method (2 tubes in series; adsorbing tube contains 400 mg charcoal and back up tube contains 200 mg charcoal). - OSHA Method (2 tubes in series; each contains 150 mg charcoal). - Qazi-Ketcham Method (1 tube; front section contains 700 mg charcoal and back up section contains 390 mg charcoal).	- Desorption with carbon disulfide and gas chromatographic determination. or - Thermal desorption and gas chromatographic determination.	Advantages - Small, portable sampling device. - Minimal interferences. Disadvantages - Breakthrough can occur. - In areas with greater than 60 percent relative humidity, 10 to 40 percent ETO loss found with sample volume >10 liters. - Not suitable for extremely short sampling periods (< 15 min.) - Requires cold transportation and storage conditions.	Amato 1980; Glaser et al. 1977; NIOSH 1976; SKC 1980; Qazi and Ketcham 1977
Impinger (gas bubble tube containing liquid medium) - Romano Method (ETO converted to ETG in a 0.1N sulfuric acid solution). - Bolton Method (ETO converted to ETG in 20 percent sulfuric acid solution).	- Neutralization of absorbing acid solution with 50% potassium hydroxide and gas chromatographic determination. - Oxidation to formaldehyde and colorimetric determination based on reaction with sodium chromotropate.	Advantages - Absorption efficiency not subject to ambient air temperature or relative humidity. Disadvantages - Cumbersome sample apparatus. - Wet method analysis. (Bolton method). - Possible spillage during sampling and transfer. - Requires correction for evaporation.	Amato 1980; Glaser et al. 1977 Romano and Renner 1979; SKC 1980
Sample Bag (Tedlar)	- Gas chromatographic determination.	Advantages - Suitable for full shift or short term (5 minutes or less) samples. - No sample loss at 50 ppm ETO during 5 day storage period. - No need to transport under cold conditions. - Bags are reusable. Disadvantages - Bulky sample apparatus. - Possible penetration by sharp object.	Amato 1980; SKC 1980

potassium hydroxide and gas chromatographic determination (Romano method) or oxidation to formaldehyde which is determined colorimetrically by its reaction with sodium chromatropate (Bolton method) (Glaser et al. 1977; Romano and Renner 1979).

Alternatively, a sample bag (Tedlar bag) may be worn by the worker and connected to a sample tube which terminates near his breathing zone. The pump draws a known volume of air from the vicinity of the breathing zone into the bag where it is collected. A sample of the air mixture is then removed from the bag for gas chromatographic determination.

In general, personnel monitoring techniques have the following advantages and disadvantages (Opp 1980):

- Advantages
  - Readily portable
  - Extremely sensitive
  - Specific for ETO
  - Provide a time weighted average measure of exposure
  - Monitor actual personnel exposure
- Disadvantages
  - Require laboratory analysis
  - Time delay in obtaining results
  - Results do not specify source or event associated with exposure
  - Integrated values may mask short term exposure to high ETO concentrations

3.2 Area Monitoring

Monitoring ambient ETO concentrations in the general workplace can be performed by the use of direct reading instruments. Such instruments, whether portable or fixed continuous monitors, provide an immediate quantitative indication of the ambient ETO concentrations in the vicinity of the sample probe. The indication mechanism may be a meter, strip chart recorder, tape printout, or a color change in an indicator tube (Keenan 1973). Such equipment may be used to determine peak concentrations (within the range limits of the particular instrument), to determine changes in concentration over time, and to determine concentrations at different locations within the work area. Portable units may, in addition, be used to identify leak sites while fixed, continuous monitoring networks may incorporate an alarm to notify personnel in the event that ambient ETO concentrations exceed predetermined levels.

Table 3-2 summarizes the types of direct reading instruments currently available for ETO monitoring. For each instrument, information regarding detection range, specificity, and response time is presented.

In general, the limitations associated with such hardware are related to specificity. Most direct reading instrumentation identified in the course of this study detect contaminants other than ETO, thus providing a potentially inaccurate measurement of ambient ETO concentrations. The nature of the interfering compounds varies with the type of instrumentation (Table 3-2).

The most commonly used type of direct reading instrumentation for area monitoring of ETO concentrations is the infrared gas analyzer. Such analyzers are available as portable units from the

TABLE 3-2

SELECTED ETO AMBIENT MONITORING INSTRUMENTATION

Operating Principle	Manufacturer	Detection Range (ppm)	Specificity	Response Time	Portability	Remarks	Reference
Combustible Gas Detection	Bacharach Instrument Company	1-10,000	Detects any combustible gas.	30 seconds	Portable (5.5 lbs.).	- Factory calibrated for hexane; conversion factor used for reading other gases. - 3 scales (1-100, 1-1,000, 1-10,000) with meter readout.	Bacharach Instrument Company 1977; McDermott 1980; Opp 1980
	ENMET Corporation	1-100		Varies with application.	Portable (1.4 lbs.).	- Alarm level at 100 ppm.	Deskin 1980; Opp 1980
	Rexnord Gas Detection Products	3,000-30,000		40 seconds	Fixed.	- Remote monitoring.	Allman 1980; Opp 1980
	Bergiont Company	>50 ppm		N.I.	Portable (2 lbs.).	- Non-quantitative - Leak detection.	Gardner 1980
	Gas Tech Inc.	30-1,000		N.I.	Portable or Fixed, multipoint.	- Meter readout on portable unit. - Fixed units have lower (15-20 ppm) and upper alarm settings but no meter readout.	Pellissier 1980
Colorimetry	National Draeger, Inc.	25-500	Interference by propylene oxide, ethylene, ketones, aldehydes, or esters.	8 minutes	Portable (1 to 1.5 lbs.).	- Accurate to within 15 percent. - Read as length of discoloration along calibrated scale. - Hand operated bellow pump used to obtain grab sample.	Fleming 1980; SKC Inc. 1980
	SKC Inc.						
Flame Ionization Gas Chromatography	Century Systems Corporation	0.5-1,000 (total organic vapor)	Detects total organic vapors if GC is not used. Specific to ETO in GC mode if there are no compounds with a similar retention time in the air sample.	2 seconds (FID)	Portable (12 lbs.).	- Meter readout in FID mode. - Audible alarm. - Optional strip chart recorder. - Selective absorbent filter for isopropanol available for operation in FID mode with 30-40 second response time.	Century Systems Corporation, undated; Morris 1980; Opp 1980
Infrared Spectrophotometry	Beckman Instruments	>50	Interference by Freon® at 11.8 μm and alcohol at 3.3 μm.	1 second	Fixed.	- Process applications.	Reuben 1979; Opp 1980
	Foxboro/Wilks	1-1,000		15 seconds	Portable (18 to 32 lbs.) or Fixed, multipoint.	- Limited accuracy below 10 ppm.	Opp 1980; Vanell 1980
	Mine Safety Appliances Co.	4-12,000		45 seconds	Fixed.	-	Opp 1980
Photoionization	HNu Systems	0.1-2,000	Interference by any compound that ionizes below 0.5 electronvolts.	8 seconds	Portable (8lbs.) or Fixed.	- Requires daily recalibration.	Devney 1980; Opp 1980
Solid State Sensor	International Sensor Technology	1-150	Interference by Co_2, hydrogen, or ammonia.	60-90 seconds	Portable (3 to 4 lbs.) or Fixed.	- Non-linear scale - Slow (5 minutes) clearance to 0 when operated continuously.	Krall 1980

N.I. - No information.

Foxboro Company and as fixed, multi-point, continuous monitoring networks from Foxboro, Beckman Instruments, and Mine Safety Appliances, among others.

Infrared analyzers detect ETO concentrations in a continuous air sample by measuring the amount of infrared energy absorbed by the compound at selected infrared wavelengths. Two such wavelengths, 11.8 μm and 3.3 μm, are used for ETO monitoring. At the former wavelength, there is interference with Freon®, a common non-flammable carrier in ETO-gas mixtures (Opp 1980; Roy 1980b).

Other types of direct reading instruments available for ETO monitoring include combustible gas detectors, colorimetric indicator tubes, and instruments utilizing flame ionization and photoionization detection.

Combustible gas detectors may use resistivity or thermal conductivity as the operating principle. Resistivity instruments utilize a filament heated above the ignition point of the substance of interest. The resultant heat of combustion changes the resistance of the filament. When the filament is part of a bridge circuit, the resulting measurement of the imbalance in resistance is related to the concentration of gas in the sample mixture. Thermal conductivity instruments measure the loss of heat from a hot filamemt. The loss results in a decrease in electrical resistance in the sample cell relative to that of the reference cell (Keenan 1973). Such instruments are generally non-specific.

Direct reading colorimetric devices utilize the chemical properties of the substance of interest for reaction with a color-producing reagent. A sample of air is drawn into an indicator tube containing solid reagent chemicals by means of a hand operated pump. The resulting color change is indicative of the presence of the suspect contaminant; the concentration is read as the length of the color stain along the graduated tube (Keenan 1973). Such devices are very portable and relatively simple to operate; however, they only detect the concentration of gas in a grab sample and thus do not provide data regarding concentrations of ETO over time. In addition, false positives due to similarly reacting interferences may occur (Fleming 1980).

The flame ionization detector (FID) is a stainless steel burner in which hydrogen is mixed with the sample gas stream. Oxygen is then diffused around the jet through which the hydrogen-gas mixture flows. The mixture is ignited on a cathode tip and a loop of platinum serves as a collector electrode. The current passing across the gap between the cathode and electrode is proportionate to the number of ions generated during ignition (Keenan 1973). The FID detects total organic vapors, has a low noise level and high sensitivity, and is used as the detector in portable gas chromatographs (Glaser et al. 1977).*

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*The Century Systems Corporation offers a selective absorbant filter to be placed in the input line of FID which is designed to stop the isopronal vapor (Freon®) while permitting the ETO to pass through. Use of this filter permits continuous direct read-out of ETO in the presence of Freon® as an interference (Century Systems Corporation undated).

One manufacturer, Century Systems Corporation, recently purchased by Foxboro-Wilks, offers a portable gas chromatograph (GC) for use with their flame ionization instrument. The FID is intended to be used in a survey mode to locate the area of concentration of organic vapors. The portable GC is then used to identify the specific contaminant and determine its concentration in the sample.

Gas chromatography is a physical process for separating the components of a complex mixture. It is based on the varied affinities of the sample components for the packing materials of a particular column. The area of the peak recorded on the strip chart is used to measure the concentration of the sample component (Keenan 1973). Since every chemical has a specific and unique affinity for the packing material in the column, different chemicals are resolved into separate peaks, each at a characteristic location (in time) that allows identification of sample components.

Photoionization instruments are similar in operation to flame ionization detectors. They differ, however, in that an ultraviolet light source, rather than a flame, is used to ionize the gas molecules (Downey 1980).

3.3 Summary

Determination of ambient ETO concentrations may be accomplished by the use of personnel monitoring techniques or by direct reading instrumentation. Personnel monitoring entails the use of a collection device and subsequent laboratory analysis. Such techniques are used primarily for the determination of actual levels of worker exposure over the sample period and provide an integrated exposure value (time weighted average). These techniques, however, are limited because there is a time delay in obtaining results, the results do not specify the source or event associated with exposure, and the integrated values may mask short term exposure to high ETO concentrations.

Direct reading instruments (both fixed and portable) may be used to provide an immediate quantitative determination of ETO concentrations in the vicinity of the sample probe. Such instruments, including combustible gas detectors, colorimetric indicator tubes, and devices utilizing flame ionization, infrared spectrophotometry, and photoionization detection mechanisms, are used to evaluate the work environment and, if equipped with an alarm, to notify workers in the event that ambient ETO concentrations exceed predetermined levels. The major limitation associated with direct reading instruments is the lack of specificity; contaminants other than ETO can be detected thereby resulting in a potentially inaccurate measurement of ambient ETO concentrations.

4.0 WORKER EXPOSURE TO ETO

This section identifies the sources and circumstances associated with worker exposure to ETO and summarizes data estimating the extent of such exposure. Much of the information presented in this section is derived from published data regarding worker exposure at hospital facilities, particularly those using vacuum chambers. Limited data were available which characterize and quantify worker exposure at other sites of use. At some sites, particularly at industrial ETO facilities, monitoring programs have been conducted; however, the resulting data are typically considered to be proprietary and therefore were not made available. In addition, it was found that assessments of worker exposure were usually not conducted at other sites (see Appendix C).

Three categories of workers may be exposed to ETO: chamber operators, repair and maintenance personnel, and other workers stationed in the general vicinity of the ETO equipment. Chamber operators may be exposed to ETO while unloading the chamber and handling treated goods. Maintenance personnel may be exposed while performing routine functions such as replacing depleted sterilant cylinders and, less frequently, while performing repairs resulting from equipment breakdown or system malfunction (active exposure). These personnel, as well as others stationed in the general vicinity of ETO equipment, may be exposed to elevated ambient ETO concentrations resulting from a number of sources of release (passive exposure).

Table 4-1 summarizes data regarding worker exposure to ETO at 23 California hospitals. Included is information regarding active exposure levels to workers while unloading the sterilizer, work practices, ambient ETO concentrations at nearby workstations, and identification of some sources of ETO release to the workplace.

The following discussion of sources and circumstances associated with worker exposure to ETO differentiates between common sources (those which may occur in the normal course of ETO treatment), and uncommon events. Within each category, sources and events associated with worker exposure are discussed in temporal order.

4.1 Common Exposure Sources and Events

Common sources of ETO release to the workplace occur in the course of normal operations. Workers may be passively exposed to ETO from leaks in the gas delivery system, the chamber, and vent connections. In addition, ETO is released during the exhaust phase of the cycle from chambers which are vented to a sewer drain as well as from chambers which vent directly into the workplace.* After completion of the cycle, operators may be actively exposed to ETO when opening the chamber door, unloading treated goods, and transferring them to storage and aeration facilities. Offgassing from treated goods in storage and from unvented or poorly vented aeration cabinets may present a further source of chronic ETO release to the

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*While such leaks are not expected to occur in the normal operation of a well maintained sterilizer/fumigator, they are sufficiently common to warrant consideration as routine sources of release.

TABLE 4-1

ETO WORKER EXPOSURE AT SELECTED CALIFORNIA HOSPITALS[a]

		Average Operator Exposure During Unloading and Transfer (ppm)		Operator Practices			Background Exposure at Staff Work Stations[d] (ppm)			Sources of Workplace Release of ETO					
Hospital/Area	Equipment	Actual[b]	15-Min. TWA[c]	Waits Before Unloading	Uses Gloves	Regular In-Service Training	Before Cycle	During Cycle	After Door Opened	Supply Lines	Chamber Door	Sterilizer Vent	Aerator	PM Program[e]	Comments
1. Central Supply	AMSCO Sterilizer Hospital constructed aerator	70 for 4.5 min.	21	Yes (5 min.)	Yes	U.K.	N.D.	N.D.	10 for 5 min.	Leak	No	Vents to floor drain.	No	No	Good airflow around sterilizer and in equipment room.
Respiratory Care	3M 400 Sterilizer Castle 4041 aerator	10 for 5 min.	3	No	No	U.K.	5 for 100 min.	25 for 90 min.	20 for 10 min.	N.A.	Minor leak	No	Vents to work area.	No	Fair ventilation.
2. Central Services	AMSCO Sterilizer 3M Aerator	50 for 5 min.	17	Yes (few min.)	Yes	No	N.D.	N.D.	50 for 30 min.	No	No	Vents to floor drain.	Vents to work area.	No	Virtually no ventilation but large diffusion volume. Equipment in poor condition.
3. Central Supply	AMSCO Sterilizer AMSCO Aerator	5 for 5 min.	2	No	Yes (rubber)	U.K.	N.D.	N.D.	N.D.	3 Minor leaks	No	Vents to floor drain.	Vents to equipment room.	Yes	Excellent cross-ventilation.
4. Central Services	Castle 4040 Sterilizer 3M 400 Sterilizer Hospital constructed aerator	75 for 3 min.	15	Yes	Yes	Yes	N.D. N.D.	25 for 150 min. N.D.	N.D. 75 for 2 min.	1 Minor leak	Minor leak	Vents to floor drain in equipment room.	No	Yes	Transfer material via cart Poor airflow around sterilizer.
Operating Room	AMSCO Sterilizer AMSCO Aerator	N.D.	N.D.	Yes (60 min.)	No	U.K.	70 for 420 min.	70 for 420 min.	70 for 420 min.	3 Major leaks	No	Vents to floor drain.	No	Yes	Headaches reported. Diffusions from major leaks in equipment room into adjacent work areas. Fairly good room ventilation.
5. Central Supply	AMSCO Sterilizer AMSCO Aerator	75 for 3 min.	15	Yes	Yes	U.K.	N.D.	N.D.	N.D.	1 Minor	No	Vents to floor drain.	No	Yes	Operator reaches into chamber to unload No basket used. Large diffusion volume. Good ventilation.

TABLE 4-1 (CONTINUED)

		Average Operator Exposure During Unloading and Transfer (ppm)		Operator Practices			Background Exposure at Staff Work Stations[d] (ppm)			Sources of Workplace Release of ETO					
Hospital/Area	Equipment	Actual[b]	15-Min. TWA[c]	Waits Before Unloading	Uses Gloves	Regular In-Service Training	Before Cycle	During Cycle	After Door Opened	Supply Lines	Chamber Door	Sterilizer Vent	Aerator	PM Program[e]	Comments
Respiratory Therapy	AMSCO Portaque AMSCO Aerator	100 for 5 min.	33	No	No	Yes	8 for 420 min.	8 for 420 min.	8 for 420 min.	No	Minor leaks	No	Minor leaks	No	Poor ventilation, area never clears completely to 0 ppm.
6. Central Services	AMSCO Sterilizers (2) AMSCO Aerator	60 for 5 min.	20	Yes	Yes	Yes	N.D.	75 for 20 min.	95 for 15 min.	No	No	Leaks from vent	Vents to equipment room	Yes	Inadequate cross-ventilation.
Surgery	3M 200 Aerator 3M Aerator	100 for 5 min.	33	No	No	U.K.	55 for 420 min.	55 for 420 min.	55 for 420 min.	N.A.	No	Vents to room	Vents to work area		Heavy usage. Small room with poor ventilation.
7. Central Services	AMSCO Sterilizer AMSCO Aerator	50 for 5 min.	17	Yes (15 min.)	Yes	U.K.	N.D.	N.D.	75 for 15 min.	Leak	No	Vents to floor drain	No	Yes	Only marginal ventilation but no nearby work stations.
8. Surgery	AMSCO Sterilizer AMSCO Aerator	100 for 5 min.	33	No	Yes	U.K.	10 for 420 min.	10 for 420 min.	10 for 420 min.	No	No	Vents poorly to drain	No	No	Sterilizer located in high-traffic area. Inadequate ventilation. Not enough aerator space available.
9. Central Supply	Castle Sterilizer Castle Aerator	20 for 5 min.	7	Yes (15 min.)	No	Yes	N.D.	N.D.	45 for 20 min. 20 for 10 min. 10 for 5 min.	2 Leaks	No	Vents to floor drain	Vents to equipment room	Yes	Operators wash down sterilizers without gloves. Adequate ventilation.
10. Central Supply	AMSCO Sterilizers (2) AMSCO Aerator	25 for 3 min.	5	Yes (20 min.)	Yes	No	N.D.	N.D.	N.D.	Major leaks	1 Leak	Vents to floor drain in equipment room	Vents to equipment room	Yes	No work stations nearby. Exhaust vent located above each sterilizer.
11. Central Supply	Castle Sterilizer Castle Aerator	>100 for 5 min.	100	Yes (15 min.)	No	No	N.D.	50 for 360 min.	100 for 80 min. 50 for 100 min.	No	No	Vents to floor drain in work area	Vents to work area	Yes	Inadequate cross-ventilation. Poorly designed area. Steam vents blow ETO out of drain.

TABLE 4-1 (CONTINUED)

Hospital/Area	Equipment	Average Operator Exposure During Unloading and Transfer (ppm)		Operator Practices			Background Exposure at Staff Work Stations[d] (ppm)			Sources of Workplace Release of ETO				PM Program[e]	Comments
		Actual[b]	15-Min. TWA[c]	Waits Before Unloading	Uses Gloves	Regular In-Service Training	Before Cycle	During Cycle	After Door Opened	Supply Lines	Chamber Door	Sterilizer Vent	Aerator		
12. Central Supply	AMSCO Sterilizers (2) AMSCO Aerator	40 for 3 min.	16	Yes (15 min.)	Yes	Yes	N.D.	100 for 15 min.	100 for 30 min.	Minor leaks	No	Vents to floor drain in equipment room.	No	Yes	Inadequate cross-ventilation. Fairly even diffusion throughout entire area. Steam vents blow ETO out of drain.
13. Central Supply	AMSCO Sterilizer	5 for 5 min.	2	Yes (15 min.)	No	No	N.D.	N.D.	20 for 10 min.	No	No	Vents to floor drain in equipment room.	N.A.	Yes	No enclosed aerator. Low work load. Area well ventilated.
14. Central Sterile Procedures	AMSCO Sterilizer Anderson Sterilizer Ben Venue Sterilizer Aerator (manufacturer unknown)	40 for 5 min. 30 for 3 min.	23 —	Yes (15 min.)	No	No	N.D.	N.D.	40 for 30 min. 10 for 30 min.	No	All sterilizers leaked	Vents to drain in equipment room. Table top units unventilated.	Vents to work area.	Yes	Inadequate cross-ventilation. Aerator installation poor. Food exposed.
15. Central Supply	Castle Sterilizer Castle Aerator	N.D.	N.D.	Yes (15 min.)	Yes	Yes	N.D.	N.D.	N.D.	Major leaks	No	Vents to floor drain in equipment room.	Vents to equipment room.	U.K.	Excellent cross-ventilation.
16. Central Supply	Castle Sterilizer Castle Aerator	N.D.	N.D.	Yes (15 min.)	Yes	Yes	N.D.	N.D.	N.D.	No	No	Vents to floor drain in equipment room.	Vents to work area.	U.K.	Good cross-ventilation.
17. Central Supply	AMSCO Sterilizers (2) AMSCO Aerator	35 for 5 min.	12	Yes (15 min.)	Sometimes	Yes	N.D.	N.D.	35 for 10 min.	No	No	Vents to floor drain in equipment room.	Leaks; Vents to work area.	U.K.	Fair ventilation (5 changes/hour).

TABLE 4-1 (CONCLUDED)

Hospital/Area	Equipment	Average Operator Exposure During Unloading and Transfer (ppm)		Operator Practices			Background Exposure at Staff Work Stations[d] (ppm)			Sources of Workplace Release of ETO					Comments
		Actual[b]	15-Min. TWA[c]	Waits Before Unloading	Uses Gloves	Regular In-Service Training	Before Cycle	During Cycle	After Door Opened	Supply Lines	Chamber Door	Sterilizer Vent	Aerator	PM Program[e]	
18. Central Supply	Castle Sterilizer (1500) Castle Aerator	70 for 5 min.	23	Yes (15 min.)	Yes	No	N.D.	N.D.	30 for 15 min.	N.A.	No	Vents to work area.	Vents to work area.	U.K.	Large diffusion volume Poor ventilation Vented room air recirculates in basement Low use work area.
19. Central Supply	AMSCO Sterilizer AMSCO Aerator	75 for 10 min.	50	No	No	No	N.D.	N.D.	10 for 10 min.	No	No	Vents to floor drain.	Vents to separate area.	U.K.	Large diffusion volume. Poor cross-ventilation. Aerator located in lunchroom.
20. Central Supply	AMSCO Sterilizer	25 for 4 min.	7	No	No	U.K.	N.D.	N.D.	30 for 10 min.	No	No	Leak from sterilizer vent (100 ppm/10 min.)	Vents to equipment room.	Yes	Adequate ventilation.
21. Central Services	3M Sterilizer (200) 3M Aerator	100 for 3 min.	20	No	No	No	N.D.	N.D.	20 for 5 min.	N.A.	No	No	Poor door seal Vents to work area.	U.K.	Adequate ventilation.
22. Central Services	AMSCO Sterilizer AMSCO Areator	45 for 4 min.	12	Yes (15 min.)	Yes	Yes	N.D.	N.D.	N.D.	No	No	Vents to equipment room.	Vents to equipment room.	Yes	Operator only worker in vicinity. Good ventilation flow to entrap waste gas.
23. Central Services	Converted Castle steam sterilizer Castle Aerator	65 for 4 min.	17	Yes (15 min.)	Yes	Yes	N.D.	N.D.	65 for 4 min.	No	No	Vents to floor drain in equipment room.	Vents to equipment room.	Yes	Poor air movement in equipment room. Operator only worker in vicinity.

N.D. - Not detectable.
N.A. - Not applicable.
U.K. - Unknown.

[a] Measurements taken during site visits to 23 California hospitals using Wilks-Miran Model 103 calibrated to detect ETO concentrations in the range of 0 to 100 ppm.

[b] Estimated average over the period of the operation, derived from readings obtained in operator's breathing zone during actual unloading and transfer of the sterilized goods.

[c] Calculated 15 minute time weighted average based on actual exposure.

[d] Estimated average derived from real time readings in the breathing zone of staff members located in any nearby work stations.

[e] Regularly scheduled preventive maintenance program.

SOURCE: Adapted from Daley et al. 1979.

workplace. Finally, workers who replace emptied ETO cylinders may be actively exposed to ETO which remains in the cylinders and in the piping system. Depending upon the specific exposure source, ETO releases may be of relatively short duration or chronic.

4.1.1 Leaks from Gas Delivery Systems

Leaks from tanks, tank valves and fittings may release ETO to the workplace during the gas charge phase of the cycle. Limited information is available regarding the levels of ETO release resulting from such sources. One source reported that leaks producing instrument readings ranging from 400 to 3000 ppm were located (Glaser 1977).

Such leaks may be relatively common. Daley et al. (1979) reported that in their survey of 23 hospitals, 9 of the 27 ETO chambers examined (33 percent) were found to have leaks in the supply lines between the ETO cylinders and the sterilizer. Three of these leaks were considered to be substantial.

4.1.2 Releases During Cycle Operation

ETO releases from the sterilizer/fumigator may occur during the cycle and may result in prolonged release of ETO to the workplace. Such releases may be due to leaks in the chamber door gasket or may be inherent in the design of some atmospheric sterilization units.

4.1.2.1 Leaking Door Gaskets. Door gaskets are intended to effect a perfect door seal. With time and use, these gaskets may crack, harden, or become misshapen and may thus provide a source of ETO leakage to the workplace during the treatment cycle.

Daley et al. (1979) reported finding evidence of leaks to the chamber door at five of the 23 (22 percent) hospitals surveyed; however, levels of ETO release from these sources were considered to be relatively insignificant. Koketsu et al. (1977) reported ETO concentrations ranging from 600 to 1600 ppm around the sterilizer door at one hospital installation and concentrations of 18,000 to 20,000 ppm at the sterilizer door at a second hospital ETO chamber. In the latter facility, ETO concentrations averaging 108 ppm were recorded 3 feet away from the sterilizer over a 45 minute period during the cycle.

4.1.2.2 Unvented Atmospheric Chambers. Some unvented atmospheric chambers are not designed to provide a complete seal either during the gas charge phase or throughout the cycle. In such chambers, ETO will be released throughout the cycle and may provide a chronic source of worker exposure.

Monitoring data supplied by Ben Venue Laboratories are summarized in Table 4-2. These data indicate that ETO is released to the workplace upon piercing of the cartridge (72.8 ppm over a 12 minute sampling period) and throughout the cycle (at lower concentrations).

Similarly, the H.W. Andersen Anprolene sterilizers are designed to permit the slow diffusion of ETO to the workplace. Monitoring test results supplied by the manufacturer are summarized in Table 4-3.

TABLE 4-2

ETO RELEASED TO A WORKPLACE DURING OPERATION OF A BEN VENUE STERILIZER[a]

Event	ETO Concentration[b] (ppm)	Sample Period (minutes)
Cartridge Pierced	72.8	12
First half of exposure period	30.6	150
Second half of exposure period	5.6	150
Manual pumping action	23.4	12
Open sterilizer and remove contents	48.9	12
Treated goods and sterilizer aerating on benchtop	2.8	120
Calculated 8 hour TWA	15.62	-

[a] Sterilizer located in 7.2 cubic meter room.

[b] Integrated value over sample time period determined by NIOSH Analytical method Set T Ethylene Oxide using charcoal collection tubes.

SOURCE: Morgan (1980b).

TABLE 4-3

ETO RELEASED TO WORKPLACE DURING OPERATION OF ANPROLENE AN-70, AN-72, AND AN-74 STERILIZERS[a]

Model Tested	Event	ETO Concentration[b] (ppm)
AN-70	During cycle[c]	<2
	15 Minutes post cycle[d]	17
	Total period	<2
AN-72	During cycle[c]	<2
	15 Minutes post cycle[d]	20.3
	Total period	<2
AN-74	During cycle[c]	4
	15 Minutes post cycle[d]	57.7
	Total period	5.6

[a] Tests conducted in an 800 cubic foot room with inadequate ventilation. Sterilizers loaded with cloth, which rapidly eludes ETO, to determine worst-case post sterilization exposure. Measurements taken continuously by infrared gas analyzer equipped with strip chart recorder. Sample probe located 2 feet in front of sterilizer door.

[b] Represents total amount of ETO released to the workplace over the sample period divided by the number of minutes in the sample period.

[c] Twelve hour period.

[d] During this period the sterilizer and liner bag were opened and the contents were removed and placed on an adjacent counter.

SOURCE: Andersen (1978).

A third sterilizer model whose design results in the release of ETO during the treatment cycle is the Castle-Sybron Model 1500. In these chambers, ETO is released from the chamber vent along with the displaced air during the gas charge phase. Field tests conducted in an unventilated 1000 cubic foot room detected ETO 1 foot in front of the sterilizer over a 13 minute period after onset of the gas charge phase. Peak ETO concentrations recorded during this period exceeded 750 ppm (Bruyer 1979b). Similar field tests were conducted in an unventilated 1243 cubic foot room and detected peak ETO concentrations ranging from approximately 50 ppm to over 750 ppm (Table 4-4) (Bruyer 1979a).

4.1.3 Releases During Exhaust Phase of Cycle

In some vacuum chambers, ETO may be released to the workplace during the exhaust phase of the vacuum cycle from chambers which are vented to the sewer drain or to the workplace, and as a result of leaks to vent connections.

4.1.3.1 Discharge to Sewer Drain. Chambers which vent to the sewer drain may result in the release of substantial quantities of ETO during the exhaust phase of the cycle. Such releases occur at the gap between the vent line and the sewer drain.

Roy (1980a) reported that ETO concentrations in the vicinity of the drain have been found to be approximately 100 to 300 ppm. However, other sources reported substantially higher concentrations. Weidrich (1980) has reported that peak ETO concentrations near the

TABLE 4-4

ETO RELEASED TO WORKPLACE DURING OPERATION OF CASTLE-SYBRON 1500 ATMOSPHERIC STERILIZER

Test Condition/ Sample Location[a]	Peak ETO Concentration[c] (ppm)	Clearance Time[d] (minutes)
Entrance Door Open 12" from sterilizer door/ counter level[b]	200	8.2
12" from sterilizer door/ 54" from floor[b]	50	N.A.
12" from sterilizer door/ floor level[b]	>750	11.1
Entrance Door Closed 12" from sterilizer door/ 54" from floor[b]	70	32.3

[a] Test conducted in 1243 ft^3 room with no ventilation.

[b] Monitoring conducted with Wilks-Miran portable infrared gas analyzer.

[c] Approximation of data recorded on strip chart.

[d] Time for ambient ETO concentrations to clear to 50 ppm or below.

SOURCE: Bruyer (1979a)

drain may be as high as 5000 to 6000 ppm. A second source reported measurement of 4000 ppm at the drain. Concentrations 4 feet above the drain and 3 feet behind the sterilizer were found to be approximately 200 ppm (Ruck 1978). Similarly, Koketsu et al.(1977) reported ETO concentrations ranging from 100 to 8000 ppm at the floor drain during gas evacuation. In addition, they recorded concentrations of 140 to 160 ppm in the equipment area at the breathing zone level. It should be noted, however, that measurements taken in the equipment area behind the sterilizer may not be representative of ETO concentrations in the general work area. Frequently, particularly in hospital installations, equipment is recessed into the wall and the enclosed machinery area is maintained at a negative pressure relative to the general work area. Nevertheless, ETO released at the drain during evacuation may diffuse into the general work area and contribute to background ambient concentrations to which workers may be passively exposed (Glaser et al. 1977). No specific data were identified which estimate the extent of worker exposure resulting from ETO release at the drain.

4.1.3.2 Vacuum Chamber Vented to the Workplace. Some older, small vacuum chambers may not be installed with a fixed vent line to the atmosphere. In such installations the vent line may terminate in the workplace, either directly or into a sponge kept damp in a bucket of water. Workers may thus be exposed to the ETO which is evacuated from the chamber.

While no information was identified in the course of this study to estimate the current number of such installations, few are presumed to be in operation.*

4.1.3.3 Leaks to Chamber Vent Lines. Vent lines connected from the sterilizer to the atmosphere or sewer may leak thus releasing ETO during the exhaust phase of the cycle. Daley et al. (1979) reported that 1 of the 27 (four percent) ETO chambers examined showed evidence of such a leak. Concentrations of 100 ppm were recorded over a 15 minute period near the sterilizer vent connection.

4.1.4 Releases after Treatment Cycle

The greatest opportunity for worker exposure, both active and passive, occurs after the completion of the treatment cycle when the chamber door is opened and treated goods are unloaded. Unevacuated ETO present in the chamber rapidly disperses into the workplace when the chamber door is opened. In addition, residual ETO absorbed or entrapped in treated goods may present a further source of worker exposure.

4.1.4.1 Unloading Chamber and Transferring Treated Goods. The single greatest source of worker exposure to ETO, both active and passive, is the unevacuated ETO that is released to the workplace when the chamber door is opened at the conclusion of the cycle

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*One research facility contacted in the course of this study reported that a small vacuum chamber (3M Model 200) had, until recently, been vented into a damp sponge. Within the past year, the vent line had been redirected to exhaust gas to the outside atmosphere (Suffin 1980).

(Koketsu et al. 1977; Daley et al. 1979; Samuels and Corn 1979). The amount of ETO that is released is dependent upon the effectiveness of the chamber evacuation system, if any; the size of the chamber and the amount of ETO initially charged; the nature of the goods being treated; and the time delay between completion of the treatment cycle and opening the chamber door.

Peak concentrations recorded at the operator breathing zone have been reported to typically exceed 100 to 200 ppm and, on occasion, to exceed 500 ppm (Roy 1980a; 1980c).* Other sources reported similar findings, in some instances indicating that such peak concentrations have exceeded 1000 ppm (Glaser 1977; Ackert 1980; Weidrich 1980).** Such peak concentrations are typically recorded within 1 to 2 minutes after the chamber door is opened and generally fall to 10 ppm or less within 15 minutes (Ackert 1980; Nusbaum 1980). Table 4-5 presents monitoring data recorded with a portable infrared analyzer indicating the changes over time in ETO concentration 1 foot in front of a small (3M Model 200) sterilizer after the chamber door is opened. Additional data regarding ETO concentrations recorded at various locations in a hospital central supply facility are presented in Appendix B.

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*These data were reported for small and intermediate-sized sterilization chambers such as those typically found in hospital facilities and may not be applicable to larger sized vacuum chambers and other types of ETO containment equipment.

**Koketsu et al. (1977) reported that average peak concentrations measured in a survey of four Washington, D.C. hospitals ranged from 24 to 660 ppm.

TABLE 4-5

ETO CONCENTRATIONS RECORDED 1 FOOT AWAY FROM STERILIZER AFTER CHAMBER DOOR OPENED[a]

Time	ETO Concentration (ppm)
Initial Opening	385
2 Minutes	120
3 Minutes	96
5 Minutes	Not detectable

[a] Measurements recorded with portable infrared analyzer with sample probe located 1 foot from cabinet at breathing zone height.

SOURCE: Corn (1980).

ETO concentrations may be substantially higher if the chamber is not opened immediately upon completion of the cycle.* In such instances, the ETO concentration in the chamber increases due to the continuing offgassing of residual ETO absorbed or entrapped within the treated goods. Such increased concentrations will result in a substantially greater release to the workplace once the door is opened and may result in higher levels of worker exposure. Table 4-6 summarizes monitoring data which indicate the increased release of ETO resulting after an hour time delay in opening the chamber door after completion of the cycle.

A second source of ETO release to the workplace is offgassing from treated goods during transfer of the load to an aeration cabinet or storage facility. Koketsu et al. (1977) have monitored the area immediately around freshly sterilized goods and have reported ambient concentrations ranging from 17 ppm to 12,000 ppm. A second source reported that ETO concentrations of over 500 ppm were measured in the vicinity of products being removed from the sterilizer (Roy 1980c).

The extent to which workers may be exposed to ETO during transfer of treated goods is dependent upon the nature of the treated goods and their respective rates of offgassing, the method used to

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*Such delays may occur in facilities in which the chamber is loaded at the end of the workday and unloaded the following morning. In other facilities, such as in some libraries and museums, treated goods may remain in the chamber for up to 24 hours after completion of the cycle (see Appendix C).

TABLE 4-6

ETO CONCENTRATIONS RELEASED TO THE
WORKPLACE ASSOCIATED WITH DELAY IN DOOR OPENING

Chamber Model/Size	Sample Locations	ETO Concentrations (ppm)		Reference
		Door Opened Immediately Upon Cycle Completion	Door Opened After 1 Hour Time Delay	
3M Model 200/ 2 ft^3	- 12" from chamber/ 12" from floor[a]	28.7	23.6	Samuels and Corn 1979b
	- 12" from chamber/ midpoint of chamber[a]	57.4	289.0	
	- 12" from chamber/ 72" from floor[a]	126.0	87.6	
	- 72" from chamber/ midpoint of chamber[a]	19.8	45.6	
	- Operator Sample[b]	5.4	6.2	
	- Average Peak Concentration[c]	600	>1200	
Caste 7260/ 70 ft^3	- 12" from chamber/ 12" from floor[a]	46.6	103.6	Samuels and Corn 1979a
	- 12" from chamber/ midpoint of chamber[a]	41.8	400.6	
	- 12" from chamber/ 72" from floor[a]	411.2	1728.0	
	- 72" from chamber/ midpoint of chamber	55.4	92.9	
	- Operator Sample[b]	48.6	37.3	
	- Average Peak Concentration[c]	135.0	372.0	

[a] Five minute area samples collected by fixed charcoal tubes.

[b] Twenty minute personnel sample collected by charcoal tube affixed at operator breathing zone.

[c] Average of peak concentrations measured by portable infrared gas analyzer.

handle and transfer such goods, and the time required in transferring goods to an aerator or storage facility.

Table 4-7 summarizes data regarding actual worker exposures occurring while unloading the sterilizer and transferring the treated goods to an aeration cabinet. These data, obtained from analysis of charcoal tube personnel monitors, indicate that workers at this hospital central supply facility were exposed to ETO in the range from approximately 20 ppm to approximately 1500 ppm each time they unloaded a sterilizer. Actual aggregate exposure to ETO was dependent, to some extent, on the techniques used in transferring the treated goods and the associated time involved in the operation. For example, the worker in Sample 3, who was exposed to 108 ppm over approximately 1 minute, used a wire basket to transfer the goods from the sterilizer to the aerator while the worker in Sample 4, who was exposed to approximately 1500 ppm over approximately 3 minutes, physically handled the goods and, at one point, cradled some items in her arms while looking for available aerator space (Samuels 1978). Further, the low level of exposure experienced by the operator while unloading the 30 cubic foot sterilizer was due, in part, to the fact that the operator transferred the goods by pulling rather than pushing the cart. An infrared gas analyzer located "upwind" of the cart recorded ETO concentrations of up to 250 ppm (Samuels 1978).

4.1.4.2 Offgassing from Treated Goods in Storage. As noted above, material removed from the sterilizer contains absorbed and/or

TABLE 4-7

WORKER EXPOSURE TO ETO WHILE UNLOADING CHAMBER AND TRANSFERRING GOODS TO AERATOR

Circumstances[a]	ETO Concentration (ppm)	Sample Time (minutes)
Unloading small (2 ft^3) sterilizer and transfer of load to small aerator	511	2.5
	1080	3.0
	108	1.0
	1490	3.0
Unloading 2 small (2 ft^3) sterilizers and transfer of loads to small aerator	250	8.0
	895	3.0
Unloading 30 ft^3 sterilizer and transfer of load to large aerator	18.5	3.0

[a] These activities were performed by individual ETO sterilizer operators following different chamber unloading and materials handling procedures.

SOURCE: Samuels (1978).

entrapped ETO which offgasses to the surrounding atmosphere and can serve as an extended source of ETO release to the workplace. This is particularly applicable to facilities where treated goods are stored in a warehouse area, particularly in situations where such areas are not partitioned from the general workplace. One source reported chronic ambient concentrations ranging from 5 to 40 ppm resulting from offgassing of treated goods (Roy 1980a).*

4.1.4.3 Releases from Aeration Cabinets. Many hospital facilities utilize aeration cabinets rather than open-shelf aeration rooms to speed elution of residual ETO. If unvented or vented directly into the room where they are located, such aeration cabinets may serve as an additional source of ETO release and potential worker exposure. Glaser et al. (1977) reported that almost all aeration cabinets used in four Washington, D.C. hospitals were vented either directly into the workplace or into the equipment area behind the cabinet. Similarly, in a study of ETO facilities at 23 California hospitals, 9 of the 26 (35 percent) aeration cabinets were vented directly into the workplace and eight (31 percent) were vented into the machinery area behind the cabinet (Daley et al. 1979). Table 4-8 presents data regarding the concentrations of ETO recorded 1 foot above the vent of a 48 cubic foot aeration cabinet.**

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*The actual concentrations will vary depending upon the amount and type of sterilized goods as well as the size of the specific workplace where such treated goods are stored or handled (Roy 1980a).

**In this facility the aeration cabinet is vented to an exhaust system which removes the vented air to the outside atmosphere (Samuels 1978).

TABLE 4-8

ETO CONCENTRATIONS MEASURED AT AERATION CABINET EXHAUST VENT[a]

Time (minutes)	ETO Concentration (ppm)
Pre-fan Stage[b]	1.5 to 500
Initial Surge	>1200
1	720
2	360
3	240
5	168
15	120
25	108
30	108

[a] Sample probe located 1 foot above exhaust vent. Measurements taken with portable infrared gas analyzer.

[b] Monitoring conducted over 6 minute period during pre-fan stage.

SOURCE: Corn (1980).

4.1.5 Cylinder Changeover Operations

In addition to sources of ETO release in the course of normal operation, workers may be actively exposed to ETO while replacing drained cylinders of ETO. Because of the internal resistance in the gas delivery system, ETO cylinders and transport lines are never totally exhausted; some gas remains in the cylinder and in the piping network. This ETO is released, usually directly into the breathing zone of the worker, when the cylinder is disconnected and the gas lines are bled. Workers may be exposed to peak ETO concentrations ranging from 100 to 300 ppm while performing such operations (Roy 1980a).

4.2 Uncommon Exposure Sources

ETO release to the workplace may also result from non-routine events or sources. These are generally the result of substantial equipment malfunction and are thus likely to occur less frequently than ETO releases from more common sources.

4.2.1 Failure of Door Locking Mechanism

An imperfect door seal due to failure of the door locking mechanism may result in substantial ETO release during the entire treatment cycle. Such malfunctions are more likely to occur in older models than newer ones (Roy 1980a); however, no data were identified to estimate the frequency of such occurrences or the extent of ETO release.

4.2.2 Maintenance or Repair Work Resulting from System Malfunction

Maintenance and repair work, especially resulting from equipment breakdown or system malfunction, may result in active worker exposure to high levels of ETO. Such exposure may result from leaks, work on pressurized gas lines, and work on chambers in which the sterilization cycle may have been aborted prior to completion of the treatment cycle (Roy 1980c). No information is available to estimate the frequency or magnitude of such exposures.

4.2.3 Release of Emergency Relief Valve

All pressure vessels are equipped with an emergency relief valve which is designed to open before the pressure rating of the vessel is exceeded. Unless controlled, opening of this valve would result in the release of substantial quantities of ETO to the workplace (Roy 1980a). No information is available to estimate the likelihood of such an occurrence.

4.2.4 Major ETO Leak or Spill

Major ETO leaks or spills involving release of substantial quantities of ETO to the workplace may result from malfunctions of the tank, tank valve, tank overpressure safety valve, or from a ruptured gasline (Roy 1980a). Such releases would result in significant exposure to workers in the vicinity and may, in some situations, present an explosive hazard. No data are available, however, to estimate the likelihood of such occurrences.

4.3 Summary

Table 4-9 summarizes information regarding the sources of release and events which may result in worker exposure to ETO. Included are information regarding the extent, location, and duration of such releases as well as the nature of the exposure which may result. It should be noted that the ETO concentrations which are reported are, in many cases, recorded at the point of release rather than at the operator breathing zone. These may, therefore, not be representative of levels of actual worker exposure. Many factors, both mitigating and contributory, link ETO release to worker exposure. These include the extent, duration, and frequency of release, the location of the release relative to the worker, and the volume and ventilation characteristics of the workplace, among others.

TABLE 4-9

SUMMARY OF SOURCES AND EVENTS ASSOCIATED WITH POTENTIAL WORKER EXPOSURE TO ETO

Exposure Source or Event	Extent of ETO Release	Location of Release	Nature of Exposure	Comments	References
Common Sources					
Before Treatment Cycle					
Leaks from gas delivery system	Peak ETO concentrations ranging from 400 to 3000 ppm measured near point of release.	To workplace or recessed equipment area.	Passive exposure.	Leaks are, in part, a function of effectiveness of preventive maintenance programs.	Glaser 1977; Daley et al. 1979
During Treatment Cycle					
Leaks from door gasket	Peak ETO concentrations ranging from 600 to 20,000 ppm recorded at sterilizer door during cycle.	To workplace	Passive exposure.	Leaks are in part, a function of effectiveness of preventive maintenance programs.	Koketsu et al. 1977; Daley et al. 1979
Leaks from atmospheric sterilizers	Peak ETO released during gas charge phase ranging up to 750 ppm (Castle-Sybron Model 1500); average ETO concentrations around Ben Venue Sterilizer ranging from 5 to 73 ppm during cycle; average ETO concentrations around H. W. Andersen sterilizers range from 2 to 5 ppm during exposure phase.	To workplace.	Passive exposure.	Releases from some atmospheric chambers are due to equipment design.	Andersen 1978; Hamlin 1980b; Morgan 1980b; Bruyer 1979a;b
Discharge to sewer drain	Peak ETO concentrations up to 8000 ppm measured at floor level near drain.	To workplace or recessed equipment area at floor level.	Workers in general work area may be passively exposed if ETO refluxes into work area.	Equipment areas are frequently partitioned off and maintained at negative pressure relative to general work area.	Koketsu et al. 1977; Roy 1980a; Ruck 1978; Weidrich 1980
Chambers vented to workplace	N.I.	To workplace.	Passive exposure.	Limited numbers of small vacuum chambers installed without fixed vent lines to atmosphere are presumed to be in operation.	ECRI 1975
Leaks to chamber vent lines	ETO concentrations of 100 ppm recorded near sterilizer vent connection.	To workplace or recessed equipment area.	Passive exposure.	--	Daley et al. 1977

TABLE 4-9 (CONTINUED)

Exposure Source or Event	Extent of ETO Release	Location of Release	Nature of Exposure	Comments	References
Common Sources					
After Treatment Cycle					
Opening chamber door and unloading treated goods	Peak ETO concentrations up to 1000 ppm released within 1 to 2 minutes after opening chamber door; concentrations typically fall to 10 ppm or less within 15 minutes after door opening (measured directly in front of chamber door).	To workplace generally at breathing zone level.	Workers opening the chamber door and immediately unloading treated goods will be exposed to peak concentrations; other workers in the vicinity may be passively exposed to ETO which disperses into workplace.	Data are applicable to small and intermediate sized chambers typically found in hospitals. Releases from large industrial chambers and chambers which have not been opened immediately after cycle completion may be higher. Workers who manually unload chamber or who must enter chamber may be exposed to ETO for longer time periods.	Ackert 1980a; Corn 1980; Roy 1980a; Samuels 1978; Weidrich 1980
Offgassing from treated goods during transfer	ETO concentrations ranging from 17 to 12,000 ppm recorded directly above treated goods.	To workplace.	Workers transferring goods may be actively exposed; other workers in the vicinity may be passively exposed.	Duration of exposure typically limited to 10 minutes or less; aggregate exposure reduced if material handling equipment (carts, baskets) used and if transfer distance is minimal.	Koketsu et al. 1977; Roy 1980a; Samuels 1978
Offgassing from treated goods in storage	Chronic ambient ETO concentrations ranging from 5 to 40 ppm.	To storage area.	Workers stations in storage areas may be chronically exposed to elevated ETO concentrations.	Ambient ETO concentrations vary with amount and nature of goods in storage and volume and ventilation of storage area.	Roy 1980a
Unvented or poorly vented aeration cabinets	Peak ETO concentrations >1200 ppm during initial surge falling to approximately 100 ppm within 30 minutes (measured 1 foot above exhaust vent of 45 ft^3 cabinet.	To workplace or recessed equipment area.	Workers stationed in general workplace may be passively exposed if ETO concentrations accumulate.	--	Corn 1980
Other					
Cylinder changeover operations	Peak ETO concentrations ranging from 100 to 300 ppm.	To equipment area at breathing zone.	Workers changing cylinders may be actively exposed to ETO remaining in ETO cylinders and transport lines.	--	Roy 1980

TABLE 4-9 (CONCLUDED)

Exposure Source of Event	Extent of ETO Release	Location of Release	Nature of Exposure	Comments	References
Uncommon Sources					
Failure of door locking mechanism	N.I.	To workplace.	Passive exposure.	More likely to occur in older models.	Roy 1980a
Maintenance and repair work resulting from system malfunction	N.I.	To workplace or recessed equipment area.	Maintenance personnel may be actively exposed to release from leaks or while working on pressurized gas lines or chambers.	--	Roy 1980a
Release of emergency relief valve	N.I.	To workplace or recessed equipment area.	Passive exposure to workers in area.	--	Roy 1980a
Major ETO leak or spill	N.I.	To workplace or recessed equipment area.	Active and/or passive exposure to workers in area.	--	Roy 1980a

N.I. - No information.

5.0 AVAILABLE CONTROL MEASURES TO MITIGATE WORKER EXPOSURE TO ETO

Control measures to mitigate worker exposure to ETO include engineering modifications to the sterilization/fumigation equipment, workplace design considerations, and work practices. These measures address the control of worker exposure by:

- Preventing or minimizing ETO release into the workplace
- Removing ETO at the point of release before it can escape into the work environment
- Diluting ETO which has escaped
- Isolating sources of release
- Isolating workers from sources of exposure
- Limiting the duration of worker exposure

In general, engineering modifications address specific exposure sources by preventing or minimizing the release of ETO into the workplace. Workplace design considerations primarily address passive exposure to ETO by isolating sources of exposure and by ventilation. Work practices are intended primarily to limit the magnitude and duration of worker exposure.

Specific control measures currently available to reduce worker exposure are discussed in detail below. Information indicating the effectiveness of these control measures is presented where it is available.

5.1 Engineering Modifications to Sterilization/Fumigation Equipment

Engineering modifications are applicable to the sterilization equipment as well as to accessory equipment. These modifications encompass control systems to monitor leaks in the sterilization chamber, improvements in the effectiveness of chamber evacuation systems, and modifications to chamber and aerator vent systems. Manufacturers may incorporate these modifications in the design of new equipment or make them available as retrofit options for earlier models. In some instances, modifications have been developed and implemented directly by the user. The engineering modifications identified in this study and their intended functions are summarized in Table 5-1.

5.1.1 Automatic Leak Detection Systems

Some current models of vacuum chambers incorporate leak detection systems which monitor the vacuum or pressure levels in the chamber prior to sterilant introduction and during the exposure phase and either alert the operator or automatically abort the cycle in the event of a variance in pressure. Incorporation of such monitoring systems has been facilitated by the use of microcomputer controls in some of the newer vacuum chambers such as those manufactured by AMSCO (Eagle Series) and 3M (Models 400B and 202B). Manufacturers of large industrial chambers may also incorporate such features if specified by the customer.

Controls incorporated in AMSCO Eagle Series chambers monitor the time required to attain the initial vacuum, the time required to introduce the sterilant to a predetermined pressure, and the pressure changes in the chamber during the exposure phase. If the time and pressure changes exceed predetermined levels, thereby indicating a

TABLE 5-1

SUMMARY OF CURRENTLY AVAILABLE ENGINEERING CONTROL MEASURES

Modification	Function
Automatic leak detection system	Monitor vacuum/pressure changes in sterilization chamber during cycle to detect leaks or other malfunctions.
Improved chamber evacuation system	Remove a greater proportion of the ETO present in the chamber and in treated materials prior to opening the chamber door.
Drain venting modification	Reduce the amount of ETO released at the drain during chamber exhaust.
Remote controlled door opening	Permit the operator to open the chamber door from a remote location to minimize exposure to initial peak ETO concentrations released initially upon door opening.
Chamber ventilation system	Create sufficient airflow to capture and remove ETO released upon door opening and prevent its diffusion into workplace.
Gas line check valves	Shorten the length of gas line requiring bleeding during cylinder changeover thus reducing the amount of ETO released during this operation.
Vent pressure relief valves to atmosphere	Direct ETO released in event of release of pressure relief valve to outside atmosphere.
Vent aeration cabinets to outside atmosphere	Direct ETO released from treated goods during aeration to outside atmosphere.

leakage or other abnormal condition,* an alarm is activated (Spoden 1980). The operator may then attempt to remedy the situation by further tightening the door closing mechanism, may continue the cycle by activating a reset button, or may abort the cycle.** If the situation persists, the alarm will be reactivated (Spoden 1980).

The 3M Models 400B and 202B also incorporate leak detection monitoring into the chamber design. If the initial vacuum level is not attained and maintained, the cycle is automatically aborted prior to puncture of the cartridge.*** In addition, if the chamber pressure approaches atmospheric levels during the cycle, indicating air seeping into the chamber, the vacuum pump is automatically activated (Ackert 1980; 3M 1978).****

Similar leak detection capabilities are offered in large, industrial, computer-controlled units such as those manufactured by

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*Excessive time required for sterilant introduction may indicate a blocked supply line as well as a leak in the chamber or in the sterilant delivery system. Excessive pressure losses during exposure may indicate a leak or may be due to greater than average absorption of the sterilant into the load being treated (Spoden 1980).

**If the cycle is aborted, the controls automatically advance the cycle through the evacuation phase before the door may be opened (Spoden 1980).

***Other possible reasons for failure to attain and maintain the vacuum level include a blocked vacuum port, a restricted vent line, an improperly functioning vacuum system, or insufficient air pressure to the air venturi vacuum pump (3M 1978).

****3M chambers use 100 percent ETO and operate under negative pressure throughout the cycle. Therefore, any leak would result in air flowing into the chamber (Ackert 1980).

Vacudyne-Altair (Skocypec 1980). These units provide a printout of all operating parameters, including vacuum/pressure levels, and are capable of notifying the operator in the event that these levels exceed expected variances.

5.1.2 Chamber Evacuation System Modifications

In the typical ETO vacuum cycle, a single post-vacuum is used to evacuate the ETO present in the chamber. Modifications to the post-vacuum phase of the cycle are intended to remove a greater proportion of ETO from the chamber to minimize the amount that is released when the chamber door is opened after completion of the cycle. Such modifications are being offered by AMSCO, Castle-Sybron, and 3M either as standard features incorporated into their current lines, as options, or as retrofit modifications. In addition, manufacturers of large industrial chambers can incorporate various features which are designed to improve the effectiveness of chamber evacuation. These features, however, are typically custom-designed to meet user specifications rather than incorporated as a standard design element.

Three approaches to improving the effectiveness of the chamber evacuation system have been identified in the course of this study: multiple post-vacuum, pulsating post-vacuum, and air wash. The characteristics of these alternative approaches along with the chamber models for which they are applicable are summarized in Table 5-2 and discussed below.

TABLE 5-2

SUMMARY OF AVAILABLE MODIFICATIONS TO CHAMBER EVACUATION SYSTEMS

Modification	Description of Operation	Manufacturers and Models
Multiple Post-Vacuums	Typical evacuation process (evacuate chamber to predetermined vacuum level; introduce air to atmospheric pressure) is automatically repeated for predetermined number of times	AMSCO (Eagle Series) Up to 15 post-vacuums included as standard feature AMSCO (Medallion Series) 2 post-vacuums included as standard feature Beverly Pacific dependent upon customer specification Vernitron-(custom chambers) included as standard feature Vernitron-(standard chambers) expect to include as standard feature
Pulsating Vacuum	Vacuum operated intermittently during up to 30 minute chamber evacuation period (vacuum pump operates for 30 seconds; air introduced for 30 seconds), with each successive vacuum pulse creating a slightly deeper vacuum level in the chamber.	Castle-Sybron available as option for new chambers (other than Model 1500) and as retrofit package for existing installations
Air Wash	Continuous passage of air through closed chamber	
Continuous Purge	Chamber evacuated to predetermined level; air introduced into chamber while vacuum system continues to operate thereby creating airflow through the chamber. Airflow continues until chamber door is opened.	3M Corp. (Models 400B and 202B) included as standard feature 3M Corp. (Models 400 and 202) available as retrofit package
Chamber Circulation System Modification by addition of inlet and exhaust valves.	Circulator component operates after evacuation process to draw air into the inlet valve, through the chamber, and out the exhaust valve.	Large Industrial Chambers chambers with recirculating systems may be retrofitted

5.1.2.1 Multiple Post-Vacuums. Multiple post-vacuums entail the automatic repetition of the post-vacuum sequence for a predetermined number of times. Each successive vacuum is designed to remove an additional proportion of the ETO present in the chamber; the proportion removed is directly related to the depth of vacuum created in the chamber. Such evacuation systems are available on chambers manufactured by AMSCO, Beverly Pacific, and Vernitron.

AMSCO chambers have incorporated two successive post-vacuums as a standard feature since 1965; however, their most recently introduced series (Eagle Series) permits the user to select up to 15 post-vacuums (Spoden 1980). Generally, however, the manufacturer considers five post-vacuums to be sufficient (Spoden 1980).

Beverly Pacific, a manufacturer of vacuum chambers for industrial users, also incorporates multiple post-vacuums into its chamber design. The number of such vacuums is determined by the user (Sias 1980). Chambers manufactured by Vernitron for industrial users are currently available with multiple post-vacuums; however, their standard-sized chambers, intended primarily for hospital use, are typically equipped with a single post-vacuum (Kreyling 1980).*

Limited information is available to evaluate the effectiveness of multiple post-vacuums in reducing the quantities of ETO which are released into the workplace upon opening the chamber door. At present, the only available information is based on theoretical calculations of ETO concentrations present in the closed chamber at the conclusion of several successive post-vacuums (Table 5-3). These data, while verified by actual measurement (Gunther 1980), pertain to an empty chamber and do not take into account the effects of offgassing from treated material in the chamber (AMSCO 1979). Such offgassing is expected to result in higher ETO concentrations than would be present in an empty chamber (Young 1980).*

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*To date, only one hospital chamber has been constructed with a multiple post-vacuum feature (Kreyling 1980).

5.1.2.2 Pulsating Post-Vacuum. Castle-Sybron has introduced a modification to the typical post-vacuum cycle which is available as an option in new chambers and for retrofitting into existing chambers. This modification permits the vacuum pump to operate for 30 seconds and then permits air to enter the chamber for 30 seconds, with each successive pulse creating a slightly deeper vacuum. This sequence may be repeated for up to 30 minutes. Castle-Sybron recommends a 15 minute post-vacuum period for typical hospital loads while

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*AMSCO is currently engaged in a research effort to determine the extent and characteristics of ETO release under various cycle and workplace design conditions and to develop possible solutions for reducing the extent of exposure. As part of this effort, AMSCO has been monitoring ETO releases after each of the successive post-vacuums. This monitoring was initially conducted with an empty chamber and is currently being conducted with filled chambers. In addition, AMSCO is evaluating various modifications to their typical multiple post-vacuum evacuation system. For example, one modification being evaluated entails incorporation of a time delay between the successive post-vacuums. As the research effort is currently in process, no specific data were made available; however, AMSCO anticipates completion of the project and publication of findings during the spring of 1981 (Gunther 1980; Spoden 1980; Young 1980).

TABLE 5-3

ETO CONCENTRATIONS IN CLOSED CHAMBER AFTER SUCCESSIVE POST-VACUUMS[a]

Number of Post-Vacuums	ETO Concentration (ppm)
1	26,000
2	2,600
3	260
4	26
5	2.6

[a] Theoretical concentrations in empty chamber after completion of cycle and prior to opening chamber door. These levels do not account for offgassing of residual ETO from treated products.

SOURCE: Adapted from AMSCO 1979.

a longer period is recommended for material which offgasses more rapidly (Weidrich 1980). As of July 1980, such modifications have been made to 30 chambers (Frechette 1980).

The effectiveness of the pulsating post-vacuum in reducing the quantity of ETO that is released to the workplace has been evaluated independently and by the manufacturer. The results of these evaluations are summarized in Table 5-4.

The data reported by Samuels and Corn (1979b) indicate that implementation of a pulsating post-vacuum was associated with an approximately 52 percent reduction in average ambient concentrations of ETO for the first 5 minutes after door opening* and an approximately 86 percent reduction in operator exposure.** The peak values recorded were approximately 54 percent lower after the chamber modification.*** These findings, however, were only applicable when the chamber door was opened immediately upon cycle completion. When treated materials were left in the closed chamber after completion of the cycle, ETO concentrations were found to increase due to the continued offgassing and the ambient ETO concentrations rose accordingly when the door was opened.

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*This represents the average of four fixed, 5 minute samples collected in charcoal tubes.

**The operator sample was collected for 20 minutes after door opening.

***Measurements were taken with a Wilks-Miran portable infrared gas analyzer.

TABLE 5-4

EFFECTIVENESS OF PULSATING POST-VACUUM IN REDUCING EXPOSURE TO ETO

Model Tested	Method and Location of Sampling	Measurement Criteria	ETO Concentrations (ppm)								Reference
			Without Modification		With Modification						
			Door Opened Immediately Upon Cycle Completion	One Hour Time Delay In Door Opening	Door Opened Immediately Upon Cycle Completion	One Hour Time Delay In Door Opening	Three Hour Time Delay In Door Opening	Eight Hour Time Delay In Door Opening	Twelve Hour Time Delay In Door Opening	Sixty-two Hour Time Delay In Door Opening	
Castle 7260[a] 70 ft^3	Charcoal Tube Samples										
	12" from chamber/ 12" from floor	5 minute TWA	46.6	103.6	21.8	86.6	-	-	-	-	Samuels and Corn 1979
	12" from chamber/ midpoint of chamber	5 minute TWA	41.8	400.6	25.4	77.8	-	-	-	-	
	12" from chamber/ 72" from floor	5 minute TWA	411.2	1728.0	196.8	1285.4	-	-	-	-	
	72" from chamber/ midpoint of chamber	5 minute TWA	55.4	92.9	22.4	121.8	-	-	-	-	
	Relative Value[b]		138.8	581.3	66.6	392.9	-	-	-	-	
	Operator Sample[c]	20 minute TWA	48.6	37.3	6.8	26.7	-	-	-	-	
	Infrared Gas Analysis	Average peak concentration[d]	135.9	372.0	62.5	390.0	-	-	-	-	
	12" from chamber/ midpoint of chamber	20 minute TWA	31.8	53.8	11.6	37.7	-	-	-	-	
Castle 4040 39 ft^3	Infrared Gas Analysis 12" from chamber at chamber floor level	Peak concentration	1000	-	4-30[e]	-	15[f]	Not detectable	Not detectable	1000[g]	Bruyer 1978

[a] Chamber modified with 15 minute pulse.

[b] Average of all area 5 minute TWA.

[c] Operator monitored while following standard protocol as follows: fully open sterilizer door, return to work station at least 10 ft. away from the sterilizer for a prescribed time period (5 minutes for test cells with modification and 15 minutes for test cells without modification), return to remove load and position in aerator cabinet, return to work station until completion of 20 minute sample period.

[d] Average of duplicate tests.

[e] Post-vacuum tested with 15, 10, and 5 minute pulse.

[f] Five minute pulse.

[g] Post-vacuum tested with 30 minute pulse.

These findings, suggesting a reduced effectiveness if the chamber door is not opened immediately upon cycle completion, are not supported by data supplied by Castle-Sybron. Their findings indicate that peak values were reduced to negligible levels for a period of up to 12 hours after cycle completion. After 62 hours, however, the peak values were equivalent to those reported for a standard evacuation cycle (Bruyer 1978). Castle-Sybron suggested that the discrepancy between their findings and those reported by Samuels and Corn (1979b) may have been due to differences in the nature of the test loads (Weidrich 1980).

A third evaluation of this modification has been conducted at the Walter Reed Army Medical Center. The area in front of the chamber was monitored using a Wilks-Miran portable infrared gas analyzer at a point 6 inches from the door and at shoulder height. Immediately upon door opening, peak ETO concentrations were found to be 18 ppm. Within seven minutes after door opening these concentrations dropped to 15 ppm and subsequently to 3 ppm within 15 minutes after door opening (McLeod 1980). No comparable data are available for ETO concentrations prior to implementation of the modification.

5.1.2.3 Air Wash. A third approach to improving the effectiveness of the chamber evacuation system entails permitting air to continuously flow through the chamber for a specified time period. This may be accomplished by operating the vacuum pump while permitting air to enter the chamber or by the addition of diversionary valving to the chamber recirculation system. The latter method is only applicable to large industrial chambers whose design includes such a system.*

Continuous Purge. The 3M Company has incorporated a continuous purge evacuation system in all Model 400B and 202B chambers and in some Model 400 and 202 chambers.** This modification is also available for retrofitting into Model 400 and 202 chambers which were manufactured prior to the development of this feature.***

The continuous purge evacuation system, otherwise referred to as an air wash or air flush, entails the continuous passage of filtered air through the chamber. At the conclusion of the exposure phase, a vacuum of approximately 25 inches Hg is created. When this vacuum level is reached, a valve is opened to admit filtered air into the chamber while the vacuum system continues to operate. During the purge phase, which continues for a minimum of 15 minutes, a shallow vacuum is maintained within the chamber. At the conclusion of the time period, a buzzer is sounded to notify the operator that the cycle is completed. If the chamber door is not opened at that time, the purge will continue until the operator presses a designated switch and unlocks the door (3M 1978). This feature is designed to prevent accumulation of ETO in the chamber due to offgassing from treated materials (Ackert 1980).

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*The primary function of the recirculation system is to prevent stratification of the sterilant/air mixture during exposure and to facilitate homogeneous temperatures in the chamber.

**Models 400B and 202B were introduced in late 1978, Model 400 in 1969, and Model 202 in 1974. Of the total production of Model 400 units, only the last of the nine lots manufactured incorporated the continuous purge feature. Approximately one-third of the production of Model 202 chambers incorporated this feature (Ackert 1980).

***Retrofit packages are not available for Models 100 and 200 which were sold prior to 1974. Rather, 3M offers a trade-in allowance towards purchase of a new 3M chamber (Ackert 1980; Mack 1980).

The continuous purge evacuation system has been further modified in Models 400B and 202B by heating the air which is purged through the chamber. The elevated temperature facilitates offgassing and, in effect, converts the sterilization chamber into an aeration cabinet (Ackert 1980; Samuels and Corn 1980).*

A 3M Model 400B equipped with the continuous purge feature was evaluated by Samuels and Corn (1980) to determine the amount of ETO released into the workplace. This evaluation did not compare ETO concentrations prior to and after implementation of the modification as the continuous purge feature was an integral part of the chamber design. Instead, it compared the peak ETO concentrations recorded for two test cells: chamber door opened immediately upon cycle completion and chamber door opened after 1 hour time delay.

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*3M is currently developing a chamber which would be used both for sterilization and aeration. This would be accomplished by modifications which would enable the purge to continue for a sufficient time period to thoroughly aerate the treated goods. This type of equipment would eliminate the opportunity for worker exposure occurring during chamber unloading and transfer of treated goods, however, it would also limit the volume of goods that could be potentially treated (Ackert 1980).

Data summarized in Table 5-5 indicate that the continuous purge feature was associated with the release of negligible concentrations of ETO to the workplace. Average peak concentrations for both test cells were approximately 6 ppm, and 20 minute time weighted averages were calculated to be less than 1 ppm. Analysis of these samples, both fixed and personnel, indicated undetectable ETO concentrations (Samuels and Corn 1980).*

While the continuous purge feature is currently commercially available only for specific 3M models, one source reported the successful in-house modification of a number of chambers of various sizes produced by different manufacturers. The chambers, ranging from tabletop to 70 cubic foot units and manufactured by AMSCO and Castle-Sybron, were modified by company technicians to incorporate a 30 minute continuous purge evacuation cycle. The modification was found to be "very effective" in reducing the amount of ETO released when the chamber door is opened. It was further found to have reduced the amount of ETO subsequently released from offgassing by approximately 80 percent (Roy 1980a). More specific data were not made available.**

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*The lower detectable limits for this method were calculated to be 8 ppm for the 5 minute fixed sample and 2 ppm for the 20 minute operator sample (Samuels and Corn 1980).

**Prior to implementation of any modifications, peak concentrations measured in the breathing zone were reported to exceed 100 to 200 ppm upon door opening (Roy 1980a).

TABLE 5-5

EFFECTIVENESS OF CONTINUOUS PURGE EVACUATION SYSTEM IN REDUCING WORKER EXPOSURE TO ETO

Measurement Criteria	ETO Concentrations (ppm)[a,b]	
	Door Opened Immediately After Cycle Completion	One Hour Time Delay in Door Opening
Average Peak Concentration[c]	6.5	6.3
5 Minute TWA	2.9	3.1
10 Minute TWA	1.5	1.5
20 Minute TWA	0.7	0.8

[a] Evaluation conducted using Wilks-Miran portable infrared gas analyzer positioned 12 inches from the chamber and at the chamber midpoint and reading for 20 minutes after door opening.

[b] Charcoal tubes were also used to collect samples at four fixed locations and as a personnel sampler. Analysis of the samples indicated undetectable levels of absorbed ETO. The lower detectable levels for this method are 8 ppm for fixed samples and 2 ppm for operator breathing zone samples (Samuels and Corn 1980).

[c] Average of duplicate tests.

SOURCE: Samuels and Corn 1980.

Modification to Chamber Recirculating System. Some large industrial chambers include a recirculating system to prevent stratification of the sterilant mixture and to enhance temperature uniformity during the exposure phase. This recirculating system can be modified by the incorporation of three valves: one in the recirculating line, an inlet valve, and an exhaust valve. During the exposure phase the latter two valves remain closed while the former one is opened. After normal evacuation, the inlet and exhaust valves automatically open and admit air into the chamber. The air is drawn across the chamber and exits via a discharge line directed outside the building (Markinson 1980b).* No data were available regarding the ETO concentrations that would be released to the workplace after implementation of this modification.

5.1.3 Liquid/Gas Separator

Addition of a liquid/gas separator into the venting systems of chambers which exhaust to the sewer drain is intended to reduce the amount of ETO which is released at the drain during the exhaust phase of the sterilization cycle.

This modification is available from Castle-Sybron for retrofitting into existing installations and as an optional feature in new units.* The separator is installed in the exhaust line of the sterilizer beyond the vacuum pump. The water/gas mixture enters the separator tangentially thus creating a swirling action which separates the entrained gas from the water. The water is then directed downward to the sewer and the gas is directed to the atmosphere via a vent line (Castle-Sybron 1980a).

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*The circulators which are used to create the airflow through the chamber typically have limited air handling capacity. As such, an extended time period would be necessary to effectively flush ETO from the chamber (Markinson 1980b). No estimates of the time period required were made available.

The liquid/gas separator has been included as a standard feature in many large industrial chambers (Markinson 1980b; Sias 1980). These separators are generally not connected to an atmospheric vent line but are primarily intended to control the flow rate of the water/gas mixture to prevent excessive splashing at the drain. Such installations can be readily modified by the addition of a vent line to direct the separated gas to the atmosphere (Markinson 1980b).

One estimate indicates that, in the absence of the liquid/gas separator, approximately 95 percent of the initial sterilant charge is directed towards the sewer drain while approximately 5 percent is retained within the treated material and packaging as adsorbed or entrapped ETO. Modification of the exhaust system by the addition of a liquid/gas separator was estimated to divert 85 percent of the initial ETO charge to the atmosphere with 10 percent retained in the water (Markinson 1980b). Some of the entrained gas may be released to the workplace at the exhaust line terminus.*

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*While these units are being marketed for Castle-Sybron chambers, they are compatible with chambers from other manufacturers (Roy 1980b; Weidrich 1980).

Castle-Sybron (1980a) reported that after installation of the liquid/gas separator, ETO concentrations at the drain were approximately 50 ppm.** Another source reported that ETO concentrations were reduced by approximately 75 percent (from approximately 120 ppm to approximately 30 ppm) after installation of a liquid/gas separator on a 70 cubic foot chamber (Roy 1980a).

5.1.4 Remote-Control Door Opening

Beverly Pacific, a manufacturer of large industrial chambers, has designed a unit which incorporates a remote-controlled, hydraulically operated door.*** At the conclusion of the cycle, the door is partially opened and a diversionary fan is operated for a period sufficient to disperse the ETO present in the chamber. The door is then fully opened automatically and the operator enters the area to unload the chamber. By permitting the operator to control the chamber door from a remote location, this feature prevents exposure to the peak levels of ETO release that occur shortly after the chamber door is opened (Sias 1980). No data are available regarding levels of worker exposure associated with this modification.

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*The release of some quantities of ETO at the drain level after installation of a liquid/gas separator has been addressed by one contract sterilizer facility identified in the course of this study. At this facility, the liquid effluent, rather than being directed to the sewer, is recirculated within a closed system. This system, which entails pumping the water to a cooling tower located on the building roof prior to reuse, avoids the air gap requirement and thus the opportunity for release of entrained ETO into the workplace. This design was primarily intended to address potential water pollution regulations related to effluent discharge rather than to control ETO release to the workplace (Skocypec 1980). Other facilities have addressed the possible reflux problem by loosely enclosing the drain in a funnel (see Appendix C).

**Other tests conducted by Castle-Sybron have measured ETO concentrations 1 foot above the drain during the evacuation phase. The peak concentrations recorded in two test runs were 10 ppm and not detectable, respectively (Bruyer 1978). The results of these evaluations, however, may not be typical of actual use conditions (Weidrich 1980).

***One such chamber has been constructed to meet the design specifications of an industrial ETO user (Sias 1980).

5.1.5 Chamber Ventilation Systems

Chamber ventilation systems are designed to operate after the chamber door is opened in order to capture and divert ETO before it can escape into the general workplace. Such systems may operate for a sufficient time period after the chamber door is opened to capture the initial ETO plume or may continue to operate throughout the unloading operation.

Chamber ventilation systems for large industrial chambers utilize differential pressure to create an airflow from the workplace into the chamber. Ventilation systems for smaller chambers utilize local exhaust hoods mounted near the sterilizer door to capture and remove ETO being released.

5.1.5.1 Differential Pressure Chamber Ventilation Systems.

Differential pressure chamber ventilation systems are incorporated into large industrial chambers and operate when the chamber door is opened at the conclusion of the cycle. These modifications create a negative pressure within the chamber. Air from the workplace entering the chamber to equalize pressure creates an airflow away from the operator and removes a portion of the ETO remaining in the chamber by venting it through an exhaust port in the chamber.

These systems may continue in operation during the unloading process thereby facilitating the continuous removal of ETO from the chamber. This is particularly applicable to chamber designs which require the operator to enter the chamber in order to retrieve the treated goods.

Three variations of differential pressure ventilation systems have been identified in the course of this study. Beverly Pacific, a manufacturer of large industrial chambers, reported modification of some units by the addition of diversionary valving to the chamber recirculating system. At the conclusion of the cycle the chamber door is partially opened and the recirculating system activated. The blower component of the recirculating system creates a pressure differential in the chamber relative to that of the workplace thereby forcing air to flow into the chamber (Sias 1980).

Alternatively, the chamber vacuum system can be utilized to create the same effect. This modification, developed and currently marketed by Environmental Tectonics Corporation, incorporates a microswitch which automatically activates the vacuum system when the chamber door is opened. The modification is relatively simple to implement and may be incorporated in chambers with either automatically or manually operated doors (D'Aquila 1980). No data were available regarding the effectiveness of these modifications.

A third variation has been designed by Travenol Laboratories and built by Vacudyne-Altair. This system is being made available as an optional feature in new chambers and can be retrofitted into existing installations (Markinson 1980a).*

This system entails construction of a large opening on the roof or rear wall of the chamber. The opening is fitted with a butterfly valve and valve actuator and is connected by ducting to a fan mounted on the roof of the building. A microswitch mounted on the chamber door automatically opens the valve and activates the exhaust fan when the chamber door is opened at the conclusion of the cycle. The system is designed to create a sufficient velocity across the chamber cross-section to assure that little or no ETO is released from the chamber into the workplace and that the operator unloading the sterilizer has sufficient airflow over him to minimize his exposure to ETO (Markinson 1980b). It has been reported that implementation of this feature would reduce 8 hour time weighted average exposure to below 10 ppm (Markinson 1980a).

5.1.5.2 Local Exhaust Hoods. Local exhaust hoods are designed to capture a contaminant at or near its release source and prevent its dispersion throughout the workplace. When mounted on the chamber near the door opening, the hood serves to capture the initial plume of ETO that is released when the door is opened. If operated continuously, the hood also captures and removes ETO released due to door gasket failures or other leaks (Roy 1980a).

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*Approximately 98 percent of new chambers constructed by Vacudyne-Altair have incorporated this modification (Markinson 1980a) and approximately six retrofit installations have been made (Skocypec 1980).

Local exhaust hoods are available from Castle-Sybron and H.W. Andersen and will shortly be available from 3M. In addition, at least one industrial ETO user identified in the course of this study has designed and custom-fabricated local exhaust hoods for a number of different model chambers.

The 3M Company has designed and is currently evaluating local exhaust hoods to be made available as accessories for Models 400 and 200. These hoods, which are expected to be commercially available in late 1980, are designed to be mounted on the top of the chambers and connected to the building ventilation system. The hood is equipped with a door latch to hold the door in a partially opened position and is intended to be operated only at the conclusion of the cycle (Ackert 1980).

Evaluations of the effectiveness of this modification have been performed by the manufacturer and an independent source. While complete data were not available from 3M, it was reported that use of the local exhaust hood resulted in peak airborne ETO concentrations of approximately 1 ppm. Peak airborne concentrations without the hood were reported to range from 100 to 1000 ppm (Ackert 1980).*

An independent evaluation of a 3M Model 200 chamber equipped with a similar, though side-mounted, hood was conducted by Samuels and Corn (1979a). Their findings, presented in Table 5-6, indicate that such a modification was effective in reducing worker exposure levels and ambient concentrations of ETO. In the absence of the local exhaust, analysis of the 20 minute operator samples indicated aggregate exposure levels of approximately 5 to 6 ppm. These levels were reduced by approximately 52 to 63 percent with use of the local exhaust hood.

Use of the local exhaust hood was also associated with a substantial reduction in peak ETO concentrations. Without the modification, these levels were reported to range from 600 to over 1200 ppm. The latter values were recorded after 1 hour time delay in opening the chamber following cycle completion and reflect the accumulation of offgassed ETO from treated materials. Peak ETO concentrations recorded when the local exhaust was used were approximately 67 ppm when the door was opened immediately upon cycle completion and 62 ppm when there was a 1 hour delay in opening the chamber. It was also reported that when the local exhaust was used, the peak values were

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*Testing was conducted in a 1000 cubic foot room with 10 air changes per hour. Monitoring was conducted with an HNu photoionization instrument with the sample probe located 1 foot from the chamber door at the breathing zone level (Ackert 1980).

TABLE 5-6

EFFECTIVENESS OF A LOCAL EXHAUST HOOD IN REDUCING WORKER EXPOSURE TO ETO[a]

Method and Location of Sampling	Measurement	ETO Concentrations (ppm)			
		Without Modification		With Modification	
		Door Opened Immediately Upon Cycle Completion	One Hour Time Delay In Door Opening	Door Opened Immediately Upon Cycle Completion	One Hour Time Delay In Door Opening
Charcoal Tube Samples					
12" from chamber/ 12" from floor	5 minute TWA	28.7	23.6	not detectable	not detectable
12" from chamber/ midpoint of chamber	5 minute TWA	57.4	289.0	not detectable	not detectable
12" from chamber/ 72" from floor	5 minute TWA	126.0	87.6	not detectable	not detectable
72" from chamber/ midpoint of chamber	5 minute TWA	19.8	45.6	not detectable	not detectable
Operator Sample[b]	20 minute TWA	5.4	6.2	2	<2
Infrared Gas Analysis					
12" from chamber/ midpoint of chamber	Average peak concentration[c]	600	>1200	66.7	62.3
	15 minute TWA	24.6	55.3	6.5	1.3
	20 minute TWA	18.4	41.5	8.3	2.6

[a] Evaluation conducted for a 3M Model 200 equipped with side mounted exhaust hood connected to an existing exhaust duct. The vacuum for the exhaust was created by using compressed air directed over a small orifice in the hood (Samuels and Corn 1979b).

[b] Operator sample obtained from charcoal tube attached to lapel. Operator monitored while following standard protocol, as follows: open sterilizer door, return to work station at least 10 feet away from sterilizer for a prescribed time period, return to sterilizer to remove load and position in aeration cabinet, return to work station until completion of 20 minute sample period.

[c] Average of duplicate tests.

recorded approximately 10 to 14 minutes after the door was opened rather than within approximately 80 seconds as was found when no local exhaust was used. Based upon these findings, it was suggested that chambers equipped with local exhaust hoods be unloaded within 5 minutes of door opening to avoid operator exposure to the peak concentrations (Samuels and Corn 1979a).

A similar local exhaust is available as a standard feature for Castle 1500 chambers* and may be retrofitted onto existing installations (Weidrich 1980). The hood, which is mounted on top of the chamber, is designed to be connected to a negative pressure vent supplied by the user. It operates continuously and is intended to remove ETO escaping when the chamber door is opened or from leaks (Castle-Sybron 1980b).

ETO concentrations were measured 1 foot in front of a Castle 1500 chamber to evaluate the effectiveness of the local exhaust hood in removing ETO.** Baseline levels were established with and without operation of the room vent fan. Subsequent readings were taken after the local exhaust hood was connected to the vent duct.

When the chamber was operated with the room fan off, measurements indicated that ETO gas was being released for approximately

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*This has been available since 1980.

**The chamber was located in a room equipped with a negative pressure exhaust duct. A Wilks-Miran portable infrared gas analyzer was used to measure ambient ETO concentrations.

13 minutes during the sterilant introduction phase* and again for approximately 4 minutes after the chamber door was opened at the conclusion of the cycle. The peak concentrations recorded during both excursions were approximately 900 ppm. With the room fan operating, the initial release during the gas introduction phase was reduced to 6.3 minutes in duration with peak concentrations recorded at less than 100 ppm. A peak concentration of approximately 600 ppm was recorded upon door opening; this excursion lasted less than 1 minute. Measurements taken when the vent hood was connected to the exhaust vent indicated no detectable concentrations of ETO either during gas introduction or upon door opening (Bruyer 1979b).

A third type of commercially available ventilation hood is being marketed by H.W. Andersen Products and is designed to be used with the AN-74 sterilizer.** It consists of a rectangular sleeve into which the sterilizer is placed, a centrifugal blower, and a 12 foot flexible hose. The hose is intended to be vented through a window or wall to the outside atmosphere (H.W. Andersen Products undated b). This system is designed to operate continuously throughout the sterilization process to capture ETO which diffuses from the nongasketed sterilizer.

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*During the gas introduction phase, ETO escapes from the chamber along with the displaced air (See Section 2.1.2).

**This ventilation system may also be used with Anprolene Sterilizers AN-70 and AN-72.

Tests conducted by H.W. Andersen indicate that average ETO concentrations in the vicinity of the sterilizer were reduced over the treatment cycle from approximately 5 ppm to less than 2 ppm when the ventilation hood was used (Hamlin 1980b).

One industrial facility identified in the course of this study has designed and installed local exhaust hoods on all their sterilizers.* The hoods included top-mounted canopy hoods, side draft, and bottom draft slot hoods. The top-mounted canopy hood was considered to be the preferable design;** however, other configurations were necessary to accommodate various sterilizer designs (Roy 1980a).

The standard design of the canopy hood specified that the hood be mounted as close to the door opening as possible. A transparent frontpiece was installed to permit viewing of gauges and dials which are usually located above the door and a side baffle was located on the side opposite the door hinge to aid in channeling air into the canopy (Roy 1980a). Specific data were not available to indicate the exposure reduction attained with use of these local exhaust hoods.

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*In addition to the ventilation hoods mounted on the sterilization cabinets, this facility has designed and installed flanged hoods with flexible ducting in the equipment area behind the sterilizers. These hoods are intended to be used during routine replacement of emptied sterilant cylinders and in the event of a tank leak. The flexible ducting also permits repositioning of the hood so that it may be used during emergency maintenance operations (Roy 1980a).

**The canopy model was considered preferable because it has a lower hood static pressure than a high velocity slot hood and therefore required a lower airflow to capture ETO (Roy 1980a).

5.1.6 Other Engineering Modifications

In addition to the engineering controls discussed above, other measures have been reported which serve to control ETO release to the workplace. These are relatively simple and can be implemented by company personnel.

5.1.6.1 Check Valves Installed in ETO Supply Line. One-way check valves can be installed in the gas supply lines leading from the cylinders to the sterilizer. These valves, installed close to the tank connection, serve to shorten the length of line which must be bled when the emptied cylinders are replaced. This minor modification serves to reduce the amount of ETO to which the worker performing this operation is exposed. It is recommended that these valves be replaced semiannually (Roy 1980a).

5.1.6.2 Venting Chamber Pressure Relief Valve. A second modification entails connection of a vent line to the pressure relief valve on the chamber. This valve is designed to open automatically if the pressure level in the chamber exceeds specified design criteria. Should this occur during the exposure phase, ETO present in the chamber would be released into the workplace. Connection of a vent line serves to divert such released ETO to the atmosphere.

5.1.6.3 Aeration Cabinet Venting. Aeration cabinets are most typically used in hospitals to facilitate elution of ETO from treated materials and thus permit more rapid turnover of ETO sterilized goods. Such aeration cabinets may be sources of exposure if they are unvented or vented into the workplace.

Unvented aeration cabinets have been manufactured by Castle-Sybron (Model 1550)* and by 3M. The latter had manufactured such cabinets until 1978. Since that date, all 3M aeration cabinets have been manufactured with vent connections (Ackert 1980).

3M currently provides a modification which enables the previously unvented aeration cabinets to be vented to the atmosphere. This modification entails changing such units from positive pressure to negative pressure cabinets and installing an exhaust port. Approximately 3 percent of the outstanding unvented cabinets have been modified to date (Ackert 1980).

5.2 Workplace Design Modifications

Modifications to the workplace design include provision of adequate ventilation and dilution volume, isolation of exposure sources, proper location of work stations, and traffic control. These control measures are primarily directed towards minimizing airborne concentrations in the work area and limiting the number of workers who may be exposed to ETO.

5.2.1 Ventilation

5.2.1.1 General Area Ventilation. General area ventilation refers to the flushing of an entire building with large volumes of air.

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*No modification is currently available for Castle 1550 aerators. Rather, the manufacturer suggests they be placed in a well ventilated room (Castle-Sybron 1979).

Such ventilation systems prevent the buildup of contaminants by dilution. They are most applicable as control measures in situations where the quantity of contaminant generated is not excessive, the workers are generally located at a distance from the exposure source, the toxicity of the contaminant is low, and the rate of generation is relatively uniform (Mutchler 1973b).

In areas containing sterilization/fumigation equipment or treated goods in storage, general area ventilation dilutes ETO which is released into the general workplace and eventually exhausts that ETO. The effectiveness of dilution ventilation is dependent upon the quantity of ETO released, the rate of release, the volume of the workplace, and the rate of air circulation.*

The Association for the Advancement of Medical Instrumentation (AAMI) recommends a minimum of 10 air exchanges per hour** for areas in health care facilities housing ETO sterilizers or aerators. They further recommend use of a dedicated system*** to minimize opportunities for recirculation of ETO laden air to other areas in the building (AAMI 1980).

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*Ventilation engineers generally prefer to express ventilation requirements in terms of cubic feet per minute (cfm) or some other absolute unit of airflow rather than in terms of air change (Mutchler 1973b).

**This represents a modification of a previous recommendation which specified a minimum of 6 air exchanges per hour.

***A dedicated exhaust system is designed to remove air and air contaminants from a single site (whether a specific area, room, or piece of equipment).

Samuels and Eastin (1980) have evaluated the effectiveness of general area ventilation in reducing ambient concentrations of ETO. Their findings indicate an inverse relationship between the number of air exchanges per hour and ambient ETO concentrations and generally support the AAMI recommendations.

Their test protocol entailed measurement of ambient air concentrations in a 1000 cubic foot room at 5 minute intervals after a sterilizer door was opened. The initial ambient concentration generated by each load was 25 ppm. Measurements were taken with 0, 5, 10, 15, and 20 air exchanges per hour, respectively.

In the absence of any air circulation (0 air exchanges per hour), ETO ambient concentrations 15 minutes after the chamber was opened were reported to be approximately 50 ppm, indicating the accumulation of ETO in the workplace. With 5 air exchanges per hour, the ambient ETO concentrations were reduced to approximately 22 ppm. These levels were found to decrease in a linear fashion when air exchange rates where increased; levels of approximately 11, 7, and 5 ppm were associated with airflows of 10, 15 and 20 exchanges per hour, respectively.*

5.2.1.2 Local Exhaust Ventilation. Local exhaust ventilation systems are designed to capture and remove an airborne contaminant at or near its source before it is diffused into the work environment.

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*Concentrations of ETO reported here are extrapolated from a graphic presentation of the data and, as such, are approximations.

Local ventilation is the preferred approach for controlling atmospheric concentrations of airborne materials that present potential health hazards in the workplace (Mutchler 1973a; Roy 1980b; Samuels 1980).

A local exhaust system consists of a network of branch ducts, each directed to a specific exposure source. The branch ducts are, in turn, connected to a main duct which terminates in an exhaust stack to the atmosphere. A fan mounted on the roof is used to create the required airflow to effectively capture the contaminant (George D. Clayton and Associates 1973; Mutchler 1973a).

The ducting should terminate as close as possible to the source of release. In some cases, hoods or other enclosures may be used to facilitate capture of the released ETO (See Section 5.1.5.2).

Local exhaust ventilation has been suggested for the following locations in the sterilization facility: near the sterilizer door,* in the sterilizer equipment area, near the sterilizer drain vent, near tank connections to the sterilizer, and in cylinder storage areas (AAMI 1980; Nusbaum 1980a). In facilities where an aeration cabinet is either unvented or vented into the workplace, a separate branch duct with a hood or a large duct 4 inches away from the aerator vent outlet can be incorporated into the system (Nusbaum 1980a). In addition, a local exhaust duct may be located near work-stations where treated goods are inspected or samples taken for subsequent sterility testing (Nusbaum 1980a).

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*Various conflicting recommendations are offered regarding the optimum location of the duct outlet relative to the sterilizer door. One source recommends locating the duct outlet, faced with a grille, directly underneath the sterilizer door (for wall mounted units), or in the floor area below pit mounted chambers. In situations where this design is infeasible, a vertical duct located opposite the door hinge and terminating 4 inches from the floor is recommended. Locating the duct outlet above the sterilizer door is considered to be the least desirable alternative for the following reasons: (1) ETO, particularly in mixtures with Freon® is heavier than air and tends to settle at the floor level; (2) duct outlets located above sterilizers must be designed to handle a greater volume of air; and (3) duct openings located near the floor level will direct airflow away from the operator breathing zone (Nusbaum 1980a). In contrast, other sources have found that ETO vapors, while heavier than air, are carried upward by the warm air from the sterilizer chamber (Samuels and Corn 1979b). Ducts located below or alongside the door opening must be equipped with a greater airflow in order to overcome the rising plume of ETO laden air (Roy 1980a).

The specific design of a local exhaust system is largely dependent on the architectural features of the individual facility. In some instances, due to excessive distance between the sterilization area and the building exterior, local exhaust systems may be difficult to implement. In such cases it may be possible to modify existing ventilation system by extending ductwork from existing ceiling exhausts (Nusbaum 1980a).

5.2.2 Isolation

Specific aspects of the sterilization/fumigation process, or the entire process itself, may be considered a source of potential exposure. Workers may be isolated from such sources by physical barriers, such as partitions, or by distance.

5.2.2.1 Partitions. Partitions may be erected around specific exposure sources to minimize the quantity of ETO which may escape into the general work area. Areas which are particularly suitable for enclosure include the machinery area at the rear of the chamber or aerator, the drain vent area, the cylinder connection area, and the cylinder storage area. In addition, storage areas housing treated goods should be partitioned from the general work area (AAMI 1980). In addition to isolating specific aspects of the ETO facility, the entire facility can be partitioned off from other work areas and access limited to authorized personnel.

5.2.2.2 Location of Equipment and Work Station. ETO sterilizers and aerators should be located to minimize worker exposure. More specifically, it is recommended that employee work-stations, desks, washing areas, and lounge areas should not be located in the immediate vicinity of the equipment (AAMI 1980). In addition, personnel not directly involved in the sterilization process should be routed around or away from all sterilization and aeration equipment. This may be accomplished by using signs or posters, tape lines around equipment areas, or temporary partitions (AAMI 1980).

In some cases, it is further recommended that consideration should be given to relocation of equipment which cannot be effectively partitioned or otherwise isolated, such as equipment located in hallways or heavily trafficked areas.

5.3 Work Practices

Work practices, as they apply to operator training, equipment operation, material handling techniques, and equipment maintenance may reduce worker exposure to ETO. In addition, use of protective clothing[*] and respiratory equipment may be applicable.

5.3.1 Operator Training

AAMI (1980) recommendations for safe use of ETO include provisions for complete training for and supervision of personnel responsible for operating ETO equipment. Such training should cover all aspects of the treatment process, including safety factors, sterilizer operating instructions, and hazards. AAMI also recommends that a training program should be conducted by the manufacturer before a sterilizer is put into service. Subsequent training should be regularly provided on an in-service (in-house) basis for all operators.

5.3.2 Equipment Operation Procedures

Several specific work practices are recommended to reduce worker exposure while unloading the chamber. These include:

- The sterilizer door must be opened as soon as possible after completion of the cycle to prevent the build-up of ETO in the chamber due to desorption from treated goods (AAMI 1980; Samuels and Corn 1979b). This may require rescheduling to avoid completion of cycles during periods when the facility is not staffed (Samuels and Corn 1979b).
- The chamber door should be partially opened (approximately 6 inches) and the operator and any other personnel in close proximity should leave the immediate area for a minimum of 15 minutes.[**] This waiting period allows most of the

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[*] Use of protective gloves has been recommended in situations where workers come into direct contact with freshly treated goods (AAMI 1980); however, other sources consider such protective clothing to be ineffective due to the permeability of many materials to ETO (Samuels 1980).

[**] Nusbaum (1980b) recommends that after the initial 15 minute waiting period, the operator should return to open the door fully and again leave the immediate vicinity of the chamber for an additional 15 minute period.

unevacuated ETO in the chamber to dissipate into the workplace atmosphere and be diluted or removed by ventilation. In cases where local exhaust ventilation is used, the time period may be shortened (AAMI 1980).

- Chambers equipped with a purge cycle should be unloaded immediately upon opening the chamber door, since it is at this point that ETO concentrations in the chamber are at the lowest levels (AAMI 1980; Samuels and Corn 1980).

5.3.3 Material Handling Procedures

ETO exposure to workers handling treated goods as well as to other workers in the vicinity can be reduced by the rapid and effective transfer of goods from the sterilizer to the aeration chamber or storage facility. To facilitate this, the aeration or storage facilities should be located in close proximity to the sterilization chamber(s). Specific recommendations for transferring treated goods include:

- Treated items should be transferred to aeration or storage facilities without delay. The aeration capacity must meet or exceed the processing requirements of the facility (AAMI 1980).
- Personnel should avoid handling of treated goods. If handling is necessary,* protective gloves should be worn (AAMI 1980).
- Material handling equipment (i.e., baskets, rolling carts) should be used to speed the transfer process. Materials should remain in the baskets or on the carts during aeration (AAMI 1980). Hand trucks, fork lift trucks, or other material-handling equipment may be applicable for removing large loads of treated material at industrial facilities.

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*Handling of treated goods may be necessary during product inspection and removal of indicator test strips or samples for laboratory testing.

- Carts should be pulled rather than pushed to direct airflow away from the operator (AAMI 1980; Nusbaum 1980b).

5.3.4 Equipment Maintenance

A regularly scheduled preventive maintenance program is intended to minimize equipment down-time and to identify and remedy sources of possible ETO release. Such a program would include routine replacement of high wear items such as door gaskets to eliminate the possibility of worker exposure due to leaks from the chamber door seal. In addition, other potential leak sites, such as valves, fittings, and connections, should be tested for evidence of leakage. A halide leak detector[*] or soap bubble solution[**] can be used for such routine leak testing (AAMI 1980; 3M 1979; Weidrich 1978).

5.3.5 Personal Protective Equipment

Use of personal protective equipment exemplifies the principle of isolating workers from their environment. Such equipment includes protective clothing, such as gloves, goggles, and coveralls, and respiratory devices.[***]

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[*] Halide leak detectors are essentially propane torches used to detect the presence of Freon®. These detectors are not applicable for facilities using either 100 percent ETO or a carbon dioxide gas mixture.

[**] A soap and water solution is applied to potential points of leakage. The appearance of bubbles is evidence of a leak.

[***] In general, personal protective devices are intended to be used only when engineering controls cannot be used or made adequate. They are recommended for short term exposures or as a second line of defense against inadvertent or unexpected conditions (Schulte 1973).

Protective clothing is recommended for use in situations where exposure to liquid ETO is likely. Such situations include cylinder changeover, emergency repair work to a chamber, and clean-up of ETO tank spills. In such cases, it has been recommended that protective gloves, goggles, and aprons be used (3M 1979; Roy 1980a).

It has also been recommended that operators wear gloves in situations where they are required to directly handle treated goods (AAMI 1980).

Use of respiratory equipment is not generally recommended for protection against routine exposure situations; however, some industrial ETO users have implemented policies which require all workers entering an ETO sterilization area to wear air-line respirators (Abrahams 1980). More typically, respirators may be made available for use in emergency situations or maintenance and repair operations (McLeod 1980; Skocypec 1980).

5.4 Summary

Table 5-7 presents a matrix relating the available engineering, workplace design, and work practice control measures to the specific exposure sources to which they are, or may be, applicable. In general, engineering controls are specific to particular exposure sources while workplace design and work practice measures are more generally applicable.

A major part of the effort to date in addressing worker exposure has focused on exposure occurring to the chamber operator when

TABLE 5-7

SUMMARY OF AVAILABLE CONTROL MEASURES TO MITIGATE WORKER EXPOSURE TO ETO

Exposure Source or Event / Control Measure	Common											Uncommon			
	Gas Delivery System Leaks	Door Gasket Leaks	Leaks Due to Equipment Design	Discharge to Sewer Drain	Chambers Vented to Workplace	Chamber Vent Line Leaks	Unloading Chamber	Transfer of Freshly Treated Goods	Offgassing from Treated Goods in Storage	Releases from Aeration Cabinets	Cylinder Changeover Operations	Failure of Door Locking Mechanism	Maintenance or Repair Work Resulting from System Malfunction	Release of Emergency Relief Valve	Major ETO Leak or Spill
Engineering Controls															
Automatic leak detection and control system		✓										✓			
Improved chamber evacuation system							✓								
Drain venting modification (liquid/gas separator)				✓											
Remote-control door opening system							✓								
Chamber ventilation systems															
Differential pressure ventilation system							✓								
Local exhaust hood[a]		✓	✓				✓				✓	✓			
Gas line check valves											✓				
Vent connection for chamber pressure relief valve														✓	
Vent connection for aeration cabinet										✓					
Workplace Design															
General area ventilation[b]	✓	✓	✓		✓	✓		✓	✓	✓		✓			
Local exhaust ventilation[a]	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓
Partitions	✓	✓	✓	✓	✓	✓			✓					✓	✓
Location of equipment and work stations[b]	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓		✓	✓
Work Practices															
Door opening procedures							✓								
Material handling procedures								✓							
Equipment maintenance	✓	✓				✓						✓			
Protective clothing							✓	✓			✓		✓		✓
Respiratory equipment							✓				✓		✓		✓

[a] Local exhaust hoods, classified here as an engineering control measure, are integral components of an overall local exhaust ventilation system. As such, possible overlap may occur between these 2 types of control measures.

[b] General area ventilation and location of equipment and work stations are intended to control passive exposure to ETO that may result from any source of release. As such, they are generally applicable, rather than specific, control measures.

the chamber door is initially opened. Various engineering controls have been developed, including various approaches to improving the effectiveness of the chamber evacuation system, chamber ventilation systems to capture and remove ETO once the chamber door is opened and systems which permit the chamber door to be opened from a remote location. In addition, local exhaust systems, specific work practices such as procedures to be followed in opening the chamber door, and use of respiratory equipment are alternative or, in some instances, complementary approaches. Less systematic attention has been directed towards other potential exposure sources, possibly because they are less routine occurrences or less likely to result in high levels of worker exposure.

6.0 IMPLEMENTATION OF MEASURES TO CONTROL AND MONITOR WORKER EXPOSURE TO ETO AND POTENTIAL EXPOSURE SITUATIONS AT SELECTED SITES

Control techniques to minimize worker exposure to ETO have been implemented in varying degrees at the 12 user sites examined in this study. In addition, the extent of use of equipment designed to monitor environmental levels of ETO in the workplace and the extent and specific instances of worker exposure to ETO differed among and within these 12 sites.

Information was collected from individual facilities that use ETO at 12 industrial, agricultural, research, and institutional sites. These facilities were requested to supply information regarding their ETO sterilization/fumigation equipment and work practices, the extent to which they have implemented control measures to minimize worker exposure to ETO at their respective facilities, and the nature and effectiveness of any modifications made to equipment, workplace design, or work practices. In addition, information was requested on the nature and extent of any ETO monitoring programs that have been implemented and regarding any potential situations of worker exposure to ETO that have been identified.* This information is discussed below and summarized in Table 6-1. Detailed information

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*Situations of potential worker exposure to ETO were also determined by MITRE based upon the engineering modifications (and equipment descriptions), workplace design, and work practices reported by the individual facilities at each site of use. Identification of such situations does not indicate that individual facilities regarded these situations as potential problems or hazards to their employees.

TABLE 6-1

SUMMARY OF EXTENT OF IMPLEMENTATION OF MEASURES TO CONTROL AND MONITOR WORKER EXPOSURE TO ETO AT SELECTED SITES (BY NUMBER)[a]

Extent of Implementation / Site Categories	Total Number	Control Measures[b]															Monitoring of Worker Exposure to ETO[c]
		Engineering Modifications							Workplace Design			Work Practices					
		Automatic Leak Detection System[d]	Chamber Evacuation System (includes multiple or pulsating post-vacuums or air wash)	Liquid/Gas Separator[e]	Remote Control Door Opening[f]	Chamber Ventilation System (includes differential pressure chamber ventilation system or local exhaust hood)	Gas Line Check Valves	Aeration Cabinet Venting System[g]	General Area Ventilation System	Local Exhaust Ventilation System	Isolation (includes use of partitions or location of equipment or work stations)[i]	Operator Training (provided either by chamber manufacturer, accredited organization, or under in-house supervision)	Equipment Operation Procedures	Material Handling Procedures	Regularly Scheduled Program of Equipment Inspection and Maintenance	Personal Protective Equipment	
Health Care and Health Diagnosis and Treatment Facilities[h]	65	3	37	3	0	2	1	43	49	9	54	60	51	33	56	47	41
Medical Products Industry	26	1	22	2	0	3	0	3	24	3	18	26	22	20	25	19	24
Libraries	12	0	5	0	0	0	0	0	0	2	3	9	6	0	2	1	1
Museums	7	0	4	2	0	0	0	0	4	0	2	5	3	1	2	2	3
Research Laboratories (Microbiological and Cancer, and Animal Breeding)	6	0	3	1	0	1	0	0	4	2	2	3	1	0	3	2	3
Transportation Sites[j]	1	NA	NA	NA	NA	NA	NA	NA	NA	NA	1	1	1	NA	NA	1	1
Beekeeping Industry	17	0	9	0	0	1	0	NA	2[k]	0	13	2	15	5	17	3	1.
High Containment Research Laboratories (in agriculture)	3	0	2	NA	0	0	0	NA	3	0	1	3	1	0	2	1	1
Animal and Plant Service Quarantine at Ports of Entry[l]	8	NA	NA	NA	NA	NA	NA	NA	1	8	7	8	8	7	NA	7	1
Spices, Seasonings, and Black Walnut Meats Industry	21	1	18	2	1	0	0	NA	16	5	16	20	18	16	19	13	12
Cosmetics Industry[m]	5	0	5	5	0	0	0	NA	5	0	5	5	5	5	5	0	5
Dairy Packaging Industry[m]	5	0	5	5	0	0	0	NA	5	0	5	5	5	5	5	0	5

TABLE 6-1 (CONCLUDED)

[a] Extent of implementation is shown in terms of the number and percent (number/percent) of facilities at each site of ETO use that implements the control and monitoring measures.

[b] These control measures are discussed in Section 5.0.

[c] Data on the different types of monitoring techniques, and on their respective advantages and limitations, are presented in Section 3.0.

[d] This system is commercially available in sterilizers manufactured by 3M (Models 202B and 400B) and AMSCO (Eagle series). Some industrial chambers, such as those manufactured by Vacudyne Altair, may incorporate such features.

[e] A liquid/gas separator can be used on only those chambers which vent spent gas mixtures to the sewer drain. The percentages presented are the ratio of facilities using liquid/gas separators to the number of facilities that report venting spent gas mixtures to the sewer drain.

[f] This feature has been custom designed by Beverly Pacific.

[g] This system is applicable only to those facilities that use a mechanical aeration cabinet. This system is not applicable (NA) to sites where aeration takes place in aeration rooms or areas (23 medical products firms and the spice, cosmetics, and dairy packaging industries) or where aeration is conducted outdoors (transportation sites, bee keeping industry, high containment research laboratories in agriculture, and animal and plant service quarantine at ports of entry).

[h] This category represents data collected only from hospitals. It was not possible to identify health diagnosis and treatment facilities (doctors, dentists, and veterinarians in private or clinical practices) who may be using ETO sterilization equipment.

[i] One medical products industry facility reported use of a Beverly Pacific sterilizer. This facility reported that the sterilizer doors are automatically cracked open, but did not specify whether it is remotely controlled.

[j] Fumigation and aeration of railroad passenger cars are conducted without the use of any containment equipment; therefore, the control measures regarding engineering modifications, general area and local exhaust ventilation systems, material handling procedures, and equipment inspection and maintenance are not applicable (NA) to this site.

[k] Four of these facilities conduct ETO fumigation indoors. Two of these four facilities have implemented this control measure.

[l] Fumigation and aeration at this site is performed with the use of a tarpaulin; therefore, the engineering modifications and equipment inspection and maintenance work practices control measures are not applicable (NA) to this site. The general area ventilation systems control measure is applicable to the three ports of entry that conduct fumigation indoors; however, only one of these three facilities (33 percent) has implemented this control measure. The six other control measures and monitoring are applicable to all of the eight ports of entry facilities.

[m] Micro-Biotrol Company, a contract sterilizer/fumigator, fumigates approximately 80 to 84 percent of the cosmetic raw materials and 100 percent of the hardware items used by the cosmetics industry (as determined by MITRE) (Butcher and Goldgraben 1980). In addition, Micro-Biotrol sterilizes dairy packaging products (77 percent of those sterilized with ETO), spices, and medical products (Smith 1980b). These data represent the extent of implementation of control and monitoring measures at the five sterilization/fumigation facilities operated by Micro-Biotrol.

regarding each facility is presented in Appendix C. The criteria used to select the individual facilities contacted for this report are also presented below.

6.1 Health Care and Health Diagnosis and Treatment Facilities

6.1.1 Use of ETO in Health Care Facilities

ETO is used in hospitals and other health care facilities to sterilize items used in medical care that are not purchased in a sterile state and that may not be processed by steam sterilization because they will be damaged or rendered ineffective by the heat or moisture. The following section summarizes the responses of 65 health care facilities and includes responses from 62 hospitals (of 200 contacted) to an American Hospital Association (AHA) survey and three hospitals to which site visits were made.* Information obtained from the 65 facilities regarding measures implemented to control and monitor worker exposure to ETO is detailed in Appendix C (Table C-1) and discussed below.

6.1.2 Situations Associated with Potential Worker Exposure

Situations associated with potential worker exposure to ETO at health care facilities may result from a number of work practices and workplace design features.

- ETO sterilizer operators did not receive formal training in ETO sterilization procedures either from the chamber manufacturer or under "in-service" supervision at five health care facilities.

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*A total of 67 hospitals (34 percent) responded to the AHA survey. Of these, five reported no use of ETO. All 65 respondents who provided information are members of the American Hospital Association.

- Of those hospitals specifying procedures followed in operating and unloading the equipment, 3 of 54 indicated that the sterilizer was unloaded immediately upon door opening.* An additional 11 facilities did not indicate if the recommended unloading procedures were being followed.

- Nine health care facilities did not utilize a regularly scheduled program of equipment inspection and maintenance.

- Employees at many health care facilities may be exposed to ETO due to inadequate aerator venting. At eight facilities aerators are vented to the workplace or to rooms located adjacent to the workplace. At one of these eight facilities, treated materials are left in an unspecified area near the chamber to aerate when its aerators are at full capacity. Fourteen facilities did not indicate where their aerators are vented.

6.1.3 Control Measures

Sterilizer operators at many health care facilities use ETO sterilization equipment designed with certain engineering features** or follow certain work practices which serve to control worker exposure to ETO.

- Automatic leak detection systems are incorporated in the chambers used at three health care facilities (two 3M Model 400B and one AMSCO Eagle Series sterilizers). These systems monitor the vacuum or pressure levels in the chamber and either alert the operator or automatically abort the cycle in the event of a variance.

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*It should be noted that one of these three facilities reported that its chamber is equipped to perform multiple post-vacuums (which may decrease ETO concentrations released to the workplace upon opening the chamber door).

**In general, these facilities did not indicate whether the engineering features were part of the original design or were installed as a modification at a later date. Such information is presented where it is available.

- ETO sterilizers at 37 health care facilities are equipped with various types of improved chamber evacuation systems, including multiple or pulsating post-vacuums and air washes.

- Check valves have been installed in ETO supply lines at one health care facility. These one-way check valves, installed close to the tank connection, serve to reduce the amount of ETO to which the worker changing the tank cylinder is exposed by shortening the length of line which must be bled when emptied cylinders are replaced. Another facility reported the installation of ball joints in the ETO gas supply lines to achieve the same type of reduction in worker exposure.

- Aeration cabinets at 43 health care facilities are vented to the outside atmosphere.

- Use of area ventilation systems were reported by 49 health care facilities.

- Access to the ETO sterilization area is restricted or the ETO work area is isolated from other areas in the workplace at 54 of the 65 health care facilities.

- Sterilizer operators at 60 health care facilities have received training in ETO sterilization procedures either from the chamber manufacturer or under "in-service" supervision. In addition, many of these facilities have posted a list of ETO sterilizer operating procedures near the chamber.

- Sterilizer operators at 51 health care facilities leave the chamber door open at the completion of the sterilization cycle for a short period of time (to permit residual ETO gas to dissipate) before unloading the treated materials from the chamber.

- Material handling equipment, such as baskets and rolling carts, are used to transfer treated materials from the sterilizer to the aerator at 33 facilities.

- A regularly scheduled program of equipment inspection and maintenance is conducted by the manufacturer or by hospital maintenance personnel at 56 facilities.

- Personal protective equipment, including gloves, goggles, and respirators, is worn by operators while operating the chamber or while unloading or handling ETO-treated materials at 47 facilities.

6.1.4 Monitoring

Forty-one of the 65 facilities contacted reported the use of monitoring equipment to determine ambient ETO concentrations in the workplace. The types of equipment used to monitor the workplace include Wilks-Miran gas analyzers (12), Draeger multi-gas detectors (11), and gas chromatography (presumably in conjunction with personnel monitoring equipment) (6).

Two facilities reported that modifications have been made to the sterilization equipment and to room ventilation systems in response to the results obtained from monitoring of the workplace. These modifications include increasing the rate of air exchanges in the ETO work area from 6.6 to 10.3 air changes per hour, installing a pulsating post-vacuum at the completion of the sterilization cycle, and installing a reducer in the exhaust line to slow the rate of water released from the chamber. In addition, one facility plans to vent its aerator to the outside atmosphere and modify its chamber venting system (but did not specify its plans on the schedule for implementing these changes).

Specific information on the types of monitoring equipment used, the results obtained, and the modifications made to existing systems at each of the 65 individual health care facilities is detailed in Appendix C (Table C-1).

6.2 Medical Products Industry

6.2.1 Use of ETO By the Medical Products Industry

ETO sterilization has been an important factor in the development and manufacture of low cost, single use sterile medical items. Approximately 80 percent of the 25,000 finished medical devices and products manufactured by this industry are sterilized with ETO. These devices and products, which include heart pacemakers, dialyzers, respiratory care nebulizers and other products, are used primarily by hospitals and health care facilities, clinical laboratories, physicians providing services in their offices, and nursing homes (Phillips et al. 1978; HIMA 1979).

The following section summarizes the responses from 26 industrial medical-products manufacturers. Of these, 23 facilities responded to a survey conducted by the Health Industry Manufacturers Association and three provided information during site visits to their facilities. Ninety-six percent of these companies are members of the Health Industry Manufacturers Association. Information obtained from the 26 facilities with respect to measures implemented to control and monitor worker exposure to ETO is detailed in Appendix C (Table C-2) and discussed below.

6.2.2 Situations Associated with Potential Worker Exposure

Situations associated with potential worker exposure to ETO at medical products facilities may result from a number of work practices and workplace design features.

- At four medical products firms treated materials are unloaded from the sterilizer immediately after opening the chamber door.*

- Sterilizer operators enter the sterilizer to unload the treated products at 12 facilities.*

- Access to ETO sterilization areas is not limited to ETO sterilization workers or authorized personnel at five medical products facilities.

- Employees at 12 of the 26 medical products firms may be exposed to ETO due to workplace design and aeration methods. At these facilities treated materials are not aerated in separate, ventilated rooms but in the general warehouse area which is not equipped with any mechanical ventilation system (3), in warehouse areas specially designated as aeration areas but lacking special ventilation (5), or in ventilated general warehouse aeration areas (4). These 12 facilities did not report whether personnel not involved in the sterilization process were routed around or away from the aerating material, or if these areas were near walkways available for general use.

6.2.3 Control Measures

Sterilizer operators at the 26 medical products firms use ETO sterilization equipment designed with certain engineering features, work in areas with proper workplace designs, or follow certain work practices to control worker exposure to ETO.

- An automatic leak detection system which monitors the vacuum or pressure levels in the chamber and alerts the operator of abnormal equipment operations has been installed in the chamber at one medical products facility.

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*It should be noted that various types of chamber evacuation systems are utilized at these facilities which may decrease ETO concentrations released to the workplace upon opening the chamber door.

- Sterilization chambers at 22 of the 26 medical products firms are equipped to perform multiple post-vacuums or air washes at the completion of the sterilization cycle.*

- Two facilities** utilize a liquid/gas separator to reduce the amount of ETO which is released at the drain during the exhaust phase of the sterilization cycle.

- A differential pressure chamber ventilation system has been incorporated into the operation of the sterilizer at one facility. The vacuum pump is used to draw ambient air into the chamber to vent/dilute the sterilant gas remaining in the chamber at the end of the sterilization cycle.

- Local exhaust (canopy) hoods are located over 2 sterilizers (out of 17) at one facility. These hoods are designed to capture ETO as it is released from the sterilizer and prevent its dispersion throughout the workplace.

- Medical products firms employ different methods for aerating ETO-treated materials. Of the 26 firms contacted, three use aerators vented to the atmosphere, five aerate treated goods in separate rooms vented to the atmosphere, and 12 aerate the treated goods in warehouse areas that are unoccupied, isolated from other work areas, or are designated as quarantine or "on-test".***

- General area ventilation systems are used at 24 of the 26 medical products facilities.

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*Of the four other firms, two have sterilizers that draw only one vacuum, one did not report this datum, and the fourth uses the Sterijet® system to treat its materials. The operation of the Sterijet® system is explained in Section 2.2.2.

**Six facilities reported that their sterilizers are vented to the drain. Sterilizers are vented to the atmosphere at 21 facilities (of which two vent at least one of their sterilizers to the drain as well).

***Five facilities did not report where treated goods were aerated, while a sixth facility reported that its chamber is a self-contained unit and that complete aeration occurs prior to the removal of treated materials from the chamber. The chamber evacuation system at this facility incorporates two post-vacuums and one air wash.

- Local exhaust ventilation systems are used by three facilities. Upon the opening of the chamber door at one facility, a 2200 cubic foot per minute exhaust blower (which is connected to a grate-covered pit in front of the sterilizer) captures sterilant gas which may be emitted from the chamber. Another facility has a slotted "pickup" (grille) at the bottom of the door and at the floor drain which provides a rate of air exchange of 1400 cubic feet per minute.

- Access to the ETO sterilization area is restricted to authorized personnel or ETO sterilization workers at 18 facilities.

- Sterilizer operators at all 26 medical products firms have received training in ETO sterilization procedures either from the chamber manufacturer or under in-house supervision.

- Sterilizer operators at 22 of the 26 medical product firms follow specified equipment operation procedures, such as leaving the door open at the completion of the sterilization cycle for a period of time before unloading the treated materials from the chamber.

- Operators use forklifts or hand trucks to transfer treated materials from the chamber to aeration areas at 20 medical products firms. Treated materials are not, in these instances, transferred manually.

- A regularly scheduled program of equipment inspection and maintenance is utilized at 25 medical product firms. The 26th firm did not indicate whether such a program was instituted.

- Sterilizer operators at 19 facilities wear protective clothing or equipment when unloading treated materials from the chambers or when changing ETO gas cylinders. The types of equipment used include gas masks, face shields, respirators, goggles, and gloves.

6.2.4 Monitoring

Twenty-four medical products firms reported that monitoring of the workplace had been conducted to determine ambient ETO concentrations. The types of monitoring equipment used at these facilities include gas chromatographs (presumably in combination with charcoal tube personnel monitors) and Wilks-Miran infrared gas analyzers (models 101 and 103). Eleven of these facilities reported that specific changes had been made to sterilization equipment, workplace design, and work practices in response to the results obtained from such monitoring. None of these facilities, however, reported specific monitoring data either prior to or after implementation of control measures.

6.3 Libraries

6.3.1 Use of ETO in Libraries

Libraries use ETO fumigation to support the preservation and restoration of rare book collections, special collections, or archives, and to treat new library acquisitions (Goldgraben 1980).

In Preliminary Benefits Analysis of Ethylene Oxide as a Fumigant in Libraries (Goldgraben 1980), MITRE reported on the use of ETO by 27 libraries, public archives, historical societies, and other library institutions that contained a minimum of 3,500,000 volumes or rare book collections of at least 10,000 volumes (Goldgraben 1980). Those libraries that had reported an annual ETO consumption of at least 25 pounds (12 of the 17) were contacted and requested to supply additional information for this report. The information obtained from the 12 libraries with respect to measures implemented to control and monitor worker exposure to ETO is detailed in Appendix C (Table C-3) and discussed below.

6.3.2 Situations Associated with Potential Worker Exposure

Situations associated with potential worker exposure to ETO at libraries may result from a number of work practices and workplace design features.

- ETO operators did not receive formal training either from the chamber manufacturer or in an accredited safety program at 3 of the 12 libraries. While such training had been offered at the other nine libraries, descriptions of operating practices at these sites suggest that such training may not have been comprehensive or that the operator may not be adequately supervised.

- ETO fumigation chambers at five of the libraries are not opened immediately upon completion of the fumigation cycle. At these libraries, the delays range from 1 to 24 hours and may result in elevated ETO concentrations to which the operator may be exposed upon opening the chamber door.

- Chamber operators at 6 of the 12 libraries unload the treated materials from the sterilizer immediately after opening the sterilizer door.*

- At one of the libraries the operator leaves the chamber door open at the end of the cycle for 24 hours (to permit residual ETO gas to dissipate) before unloading the treated materials; however, personnel work stations are located in the same room as the open chamber (Bentley 1980).

- Chamber operators at 11 of the 12 libraries do not wear any protective clothing or equipment while operating the chamber or while unloading or handling the ETO-treated materials. Two of the facilities provide respiratory equipment for use in emergency situations.

- Ten of the 12 libraries did not utilize a regularly scheduled program of equipment inspection and maintenance. The absence of such preventive maintenance may result in leakage from the ETO chamber, gas delivery system, or vent system which may, in turn, result in potentially chronic ETO release to the workplace.

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*It should be noted that various types of chamber evacuation systems are utilized at these facilities which may decrease ETO concentrations released to the workplace upon opening the chamber door.

- Employees at many of these libraries may be exposed to ETO due to workplace design features and aeration methods. None of the 12 libraries reported use of a mechanical aerator to accelerate the elution of ETO residual gas from the treated materials. ETO-treated materials were transferred to storage areas at five libraries, to open shelves (in an un-specified area) at one library, and to a hallway until they could be shelved at a later date at another library. The other five libraries did not report the manner in which treated materials were aerated at their facilities.

6.3.3 Control Measures

Many libraries use ETO fumigation equipment designed with engineering features* or follow work practices which serve to control worker exposure to ETO.

- Fumigation chambers at 4 of the 12 libraries are equipped with multiple post-vacuum evacuation systems.
- One library had installed an internal external exhaust system in the chamber which is operated for a 12-hour period after the completion of the fumigation cycle (with the chamber door open).
- Chamber operators at nine of the libraries have received training in ETO fumigation procedures from the chamber manufacturer or under in-house supervision.
- ETO fumigation of library materials is conducted in a restricted area at three of the libraries.
- Chamber operators leave the chamber door open for a period ranging from 1 to 48 hours before unloading the treated materials at six of the libraries.

6.3.4 Monitoring

One of the 12 libraries reported the use of monitoring equipment to determine ambient ETO concentrations in the workplace. The

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*These facilities did not indicate whether the engineering measures were part of the original chamber design or were installed as a modification at a later date.

Library of Congress conducted a monitoring program in 1976 using charcoal tubes, and reported average exposure levels of 0.5 ppm (McComb 1980). None of the other 11 libraries reported the use of any monitoring equipment to determine levels of ETO in the workplace or reported any programs to evaluate situations leading to worker exposure.

6.4 Museums

6.4.1 Use of ETO in Museums

Museums use ETO as a fumigant to eliminate several types of organisms which attack a wide variety of organic materials (including ethnographic items, furniture, wooden artifacts, and textiles) and to fumigate new museum acquisitions and materials that had been loaned to other institutions (Canellos 1980).

In Preliminary Benefits Analysis of Ethylene Oxide as a Fumigant in Museums (Canellos 1980), MITRE reported on the use of ETO by 12 museums which were located in urban areas having a population of at least one million and accredited by the American Association of Museums. These museums were also selected to reflect the different types of museums, including art, science, and natural history (Canellos 1980). Those museums that reported an annual consumption of ETO of greater than 20 pounds (7 of the 12) were contacted and requested to supply additional information for this report.

The information obtained from these museums with respect to measures implemented to control and monitor worker exposure to ETO is detailed in Appendix C (Table C-4) and discussed below.

6.4.2 Situations Associated with Potential Worker Exposure

Situations associated with potential worker exposure to ETO at museums may result from a number of work practices, workplace ventilation, and location of ETO equipment in areas with unrestricted access.

- ETO chamber operators at two of the seven museums did not receive formal training either from the chamber manufacturer or in an accredited safety program. While operators at the other five museums had undergone such training, descriptions of operating practices at these sites suggest that such training may not have been comprehensive or that the operator may not be adequately supervised.

- Chamber operators at four of the museums unload the treated materials from the chamber immediately after opening the chamber door. It should be noted that various types of chamber evacuation systems (which may decrease ETO concentrations released to the workplace upon opening the chamber door) are utilized at two of these facilities; however, at the other two museums the treated goods are unloaded after having been left in a closed chamber for periods up to 48 hours after the conclusion of the fumigation cycle.

- Operators at four of the museums do not wear protective clothing or equipment while operating the chamber or while unloading or handling the ETO-treated materials. At two of these four museums, the chamber operators manually unload treated materials from the fumigation chamber.

- Four of seven museums did not utilize a regularly scheduled program of equipment inspection and maintenance.

- Five museums reported that no aeration procedures are observed.

- Six of the museums reported that ventilation in the fumigation room is limited.

- Three museums reported that ETO fumigation is conducted in unrestricted areas. At another museum, employees in a loading area adjoining the chamber room may be passively exposed to ETO due to a window-size opening between the two rooms.

6.4.3 Control Measures

Some museums use ETO fumigation equipment with specific engineering features* or follow work practices which serve to control worker exposure to ETO.

- Chambers at two of the seven museums are equipped to create five post-vacuums at the end of the fumigation cycle. At one of these museums the chamber had been modified to incorporate this feature after workplace monitoring had been conducted.
- The chambers at two museums incorporate air wash cycles of 3 hours and 24 hours, respectively.
- One museum reports use of a "back-flow" meter to monitor backups in the gas vent hose during the chamber exhaust phase.
- General area ventilation systems are used by four museums: two museums reported 10 air changes per hour in the fumigation room and 8 to 10 air changes per hour in aeration areas; fumigation is performed in a trailer equipped with four vents and a fan at the third museum; and exhaust fans are installed in the chamber room for use in the summer months at the fourth museum.
- Chamber operators at four museums have received training in ETO fumigation procedures either from the chamber manufacturer (1) or under in-house supervision (3). A fifth museum reported that its operator had been certified by the State of Delaware, but did not indicate where he had received his fumigation training.
- Operators at three museums leave the chamber door open for a period ranging from 30 minutes to at least 4 hours before unloading the treated materials.

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*In general, these facilities did not indicate whether the engineering features were part of the original chamber design or were installed as a modification at a later date. Such information is presented where it is available.

6.4.4 Monitoring

Three of the museums reported that monitoring of the workplace had been conducted to determine ambient ETO concentrations.

- One museum reported that monitoring had been conducted when the fumigation equipment was initially installed in 1976; however, monitoring data were not made available. This museum also reported use of a halide leak detector* (Brown 1980).

- One museum conducted monitoring in 1978 using a Wilks-Miran infrared gas analyzer. ETO concentrations in excess of 250 ppm were recorded upon opening the chamber door. In response to these data, this museum reported that it had modified its fumigation equipment and procedures (the only modification reported by this museum was the adjustment made to the chamber to automatically create up to five successive post-vacuums). Monitoring had not been subsequently performed to determine the effectiveness of the modifications. This museum also uses a halide detector around the chamber seals and gaskets to detect leakage.

- One museum reported that it had tested its chamber for leakage and used a gas chromatograph to analyze the samples, but did not provide additional data (Reilly 1980).

6.5 Research Laboratories

6.5.1 Use of ETO in Research Laboratories

Animal breeding facilities and microbiological and cancer research facilities use ETO as a sterilant to treat heat sensitive plastic articles, delicate electronic equipment, and prepackaged laboratory items. Animal breeding facilities, for example, require sterilized items in order to rear animals in a germ-free environment. Microbiological and cancer research laboratories require sterile equipment to prevent the contamination of cultures and laboratory equipment (Zank et al. 1980)

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*Halide detectors detect the presence of Freon®.

In Preliminary Benefits Analysis of Ethylene Oxide as a Sterilant in Research Laboratories (Zank et al. 1980), MITRE reported on the use of ETO by five animal breeding facilities and seven microbiological and cancer research facilities (Zank et al. 1980). Those research facilities that reported an annual ETO consumption of at least 20 pounds (6 of the 12) were contacted and requested to supply additional information for this report. The information obtained from the six facilities with respect to measures implemented to control and monitor worker exposure to ETO is detailed in Appendix C (Table C-5) and discussed below.

6.5.2 Situations Associated with Potential Worker Exposure

Situations associated with potential worker exposure to ETO at research facilities may result from a number of work practices and workplace design features.

- ETO sterilizer operators did not receive formal training in ETO procedures either from the chamber manufacturer or in an accredited safety program at three of the six research laboratories. While operators at the other three research facilities had undergone such training, descriptions of the operating practices at these facilities suggest that such training may not have been comprehensive or that the operator may not be adequately supervised.

- Sterilizer operators at five of the six research laboratories unload the treated materials from the sterilizer immediately after opening the chamber door. At four of these facilities this follows a period (of several hours) during which the treated materials remained in the closed chamber after the completion of the sterilization cycle.*

- Sterilizer operators at five of the six research laboratories do not wear protective clothing or equipment while operating the sterilizer or while unloading or handling the ETO-treated materials.**
- Mechanical aeration chambers are used at only one research laboratory, but this aerator is vented into the workplace. Two other research laboratories reported that ETO-treated materials are aerated in a holding area and in the sterilizer room, respectively. Three other facilities did not report the method by which they aerate ETO-treated materials.
- Three of the six research laboratories did not utilize a regularly scheduled program of equipment inspection and maintenance.
- Three research laboratories reported that ETO sterilization is conducted in unrestricted areas.

6.5.3 Control Measures

Many research laboratories use ETO sterilization equipment designed with specific engineering features*** or follow work practices which serve to control worker exposure to ETO.

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*It should be noted that the sixth research facility does allow a time delay between the opening of the door and unloading of the chamber; however, the treated materials are left in the closed chamber for a period after cycle completion (Bolte 1980).

**At one of these five facilities the operator does wear eye goggles when changing the ETO gas cylinders (Davis 1980). At the sixth research laboratory, protective equipment are not worn when loading the sterilizer (in a non-sterile area) but are worn when the sterilizer is opened (into the sterile area) (Fitch 1980).

***None of these facilities indicated whether the engineering features were part of the original chamber design or were installed as a modification at a later date.

- Sterilization chambers at three research laboratories are equipped to create multiple post-vacuums at the end of the sterilization cycle. At one of these three facilities, the post-vacuums are followed by a 30-minute air-wash cycle.

- General area ventilation systems have been installed at four research laboratories. Two facilities report air exchange rates of 6-10 changes per hour in the chamber room, while a third reports an air exchange rate of 13 changes per hour in a "clean area" into which treated materials are unloaded. At a fourth facility, the chamber room is ventilated and equipped with an exhaust fan.

- Two facilities have installed chamber exhaust systems near the chambers to capture and remove ETO contaminants before the ETO diffuses into the work environment.

- Sterilizer operators at three research laboratories have received training in ETO sterilization procedures either from the chamber manufacturer (1) or under in-house supervision (2).

- Three of the research facilities utilize a regularly scheduled program of equipment inspection and maintenance.

6.5.4 Monitoring

Three of the research laboratories reported that monitoring of the workplace had been conducted to determine ambient ETO concentrations.

- One research laboratory monitors the sterilization area with a Wilks-Miran 101 infrared gas analyzer on a continuous basis. In addition, an alarm system in the workplace is activated when ETO concentrations exceed 50 ppm. This facility reported that such levels have not been attained. Another research laboratory reported the use of an alarm system to warn the employees when ETO concentration levels exceed 50 ppm.

- One research laboratory measured the levels of ambient ETO to which its workers were exposed using an (unspecified) charcoal tube method. Samples of ambient air were taken while the operator was operating and unloading the chamber, and while changing the ETO gas cylinders. The facility reported that very low levels of ETO were detected; however, no specific data were reported. The testing was conducted in 1979.

- Another research laboratory also measured the levels of ambient ETO to which its workers were being exposed using Draeger colorimetric indicator tubes. ETO concentrations ranging from 20 to 50 ppm were detected at the breathing zone level after the chamber door was opened at the end of the cycle.

6.6 Transportation Sites

At present, ETO is used as a fumigant to eliminate serious insect and rodent infestations in railroad passenger cars. ETO is also registered as a fumigant for buses, trucks, domestic and military aircraft, ship cargo holds, and railroad freight cars; however, other methods of fumigation and pest control are used at these sites (Canellos et al. 1980).

In Preliminary Benefits Analysis of Ethylene Oxide at Transportation Sites (Canellos et al. 1980), MITRE reported on the use of ETO to fumigate railroad passenger cars operated by AMTRAK (five other rail carriers reported that they did not use ETO) (Canellos et al. 1980).

Unlike most of the other ETO user sites examined in this report (except for ports of entry), ETO fumigation at railroad sites is conducted without the use of a chamber or other type of containment equipment.* In addition, the fumigation of railroad cars is carried out by professional extermination firms whose employees follow several work practices to control worker exposure to ETO. These procedures, which are described in Appendix C (Table C-6), include:

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*ETO fumigation of railroad cars is described in Section 2.3.

- Isolation of the car to be fumigated on a separate track
- Posting of warning signs around the car during the fumigation process
- Sealing of all openings in the car, except for the exit door, with gum tape
- Utilization of protective equipment, such as gas masks, by the fumigator
- Ventilation of the car to open air at the conclusion of the fumigation process
- Employment of tester kits to monitor the interior of car to determine when the car can be returned to service.

No potential situations of worker exposure to ETO could be determined at this ETO user site.

6.7 Beekeeping Industry

6.7.1 Use of ETO in the Beekeeping Industry

The beekeeping industry uses ETO as a fumigant. It is an important tool in the prevention and control of honey bee diseases, such as American foulbrood, European foulbrood, and chalkboard. ETO fumigation is also used as an alternative to the burning of bee structures and equipment that may be contaminated with bee diseases (USDA 1978).

MITRE has contacted 17 beekeeping sites in 15 states to obtain information on their ETO operations. Preliminary information on these sites was obtained from the USDA/STATES/EPA report Assessment of Ethylene Oxide Uses in Agriculture (USDA 1978). The information obtained from the 17 beekeeping facilities regarding measures implemented to control and monitor worker exposure to ETO is detailed in Appendix C (Table C-7) and discussed below.

6.7.2 Situations Associated with Potential Worker Exposure

Situations associated with potential worker exposure to ETO at beekeeping facilities may result from a number of work practices.

- ETO operators at 14 of the beekeeping facilities did not receive formal training either from the chamber manufacturer or in an accredited safety program.
- Operators at 14 beekeeping facilities manually carry treated materials from the fumigation chamber. At two of these facilities, operators manually remove and carry these treated materials from the chamber immediately after opening the chamber door.

6.7.3 Control Measures

The beekeeping facilities contacted for this report use ETO fumigation equipment designed with engineering features or follow work practices which serve to control worker exposure to ETO.

- Fumigation chambers at 9 of the 17 beekeeping facilities are equipped with "improved" chamber evacuation systems: at eight facilities the chambers are equipped to create multiple post-vacuums at the end of the fumigation cycle and at one facility the vacuum pump is operated for a 20-minute period after the chamber door is opened.
- Fumigation is conducted outdoors at 12 of the 17 beekeeping facilities and indoors in a restricted area at one facility.
- Chamber operators leave the chamber door open for a period ranging from 5 minutes to 24 hours before unloading the treated materials from the chambers at 15 beekeeping facilities.
- Treated materials are removed from the chamber on pallets at four facilities and on carts at one beekeeping facility.

- All 17 of the beekeeping facilities reported that their fumigation chambers were on a regular program of equipment inspection and maintenance.

- Operators at three facilities wear personal protective equipment, including rubber gloves (2) and self-contained breathing apparatus or gas masks, overalls, and polyethylene gloves (1).

- ETO-treated materials are aerated at seven beekeeping sites for periods ranging from 6 hours to 48 hours.

6.7.4 Monitoring

Only one beekeeping site reported that monitoring had been performed at its facility, but did not report additional data.*

6.8 High Containment Research Laboratories in Agriculture

6.8.1 Use of ETO by High Containment Research Laboratories

High containment research laboratories in agriculture have found ETO to be an effective anti-bacterial and anti-viral agent and use ETO as a sterilant and a decontaminant. These laboratories use ETO as a sterilant to treat various instruments, plastic components, and mechanical devices; when used as a decontaminant, ETO effectively destroys the exotic pathogens studied at these laboratories (USDA 1978).

The United States Department of Agriculture maintains three high containment research laboratories which are devoted to the research and diagnosis of domestic and exotic (foreign) plant and animal disease pathogens (USDA 1978). These laboratories were contacted to obtain information on their ETO operations. The information obtained from the three facilities with respect to measures implemented to control and monitor worker exposure to ETO is detailed in Appendix C (Table C-8) and discussed below.

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*In the course of one site visit, monitoring was conducted using a Wilks-Miran infrared gas analyzer. Upon opening the chamber door, ETO concentrations at the top of the chamber opening were recorded in excess of 100 ppm, the upper limit of the scale utilized. Within 15 minutes, ETO concentrations at the operator breathing zone were recorded at approximately 3 ppm.

6.8.2 Situations Associated with Potential Worker Exposure

Situations associated with potential worker exposure to ETO at high containment research laboratories may result from a number of work practices.

- Sterilizer operators at one of the three high containment research laboratory unload the treated materials from the sterilizer immediately after opening the chamber door.*
- Sterilizer operators at one facility may, on occasion, enter the chamber to remove treated materials. These workers do not utilize protective clothing or equipment when they enter the chamber; however, the chamber is usually left open to air out overnight before the treated materials are removed.
- One of the three high containment research laboratories does not utilize a regularly scheduled program of equipment inspection and maintenance, while another facility permitted its engineering staff (untrained in ETO use and its associated health hazards) to repair the sterilization equipment.

6.8.3 Control Measures

Sterilizer operators at the three high containment research laboratories use ETO sterilization equipment designed with engineering features, work in areas with workplace designs features, or follow specific work practices which serve to control worker exposure to ETO.

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*It should be noted that two post-vacuums are drawn in this sterilizer at the conclusion of the sterilization cycle.

- Sterilizers at two facilities are equipped to draw two post-vacuums at the end of the sterilization cycle.
- All three of the facilities have instituted some type of sterilizer room ventilation system: two high containment research laboratories reported the use of mechanical general area ventilation; two facilities reported that air in their buildings is filtered through High Efficiency Performance Air (HEPA) filters; and all three facilities reported air exchange rates ranging from 5 to 15 air changes per hour in the chamber rooms.
- Sterilizer operators at all three high containment research laboratories have received training in ETO sterilization procedures under in-house supervision. Operators at one facility are designated as safety technicians.

6.8.4 Monitoring

Only one of the high containment research laboratories reported that it has conducted monitoring in the workplace, specifically to detect leaks. This facility checked its five ETO sterilizers with detection devices that were sensitive to leaks at a rate of 10^{-7} cubic centimenters per second. This facility did not specify either the equipment that was used or the results obtained (Irish 1980).

6.9 Animal and Plant Service Quarantine at Ports of Entry

6.9.1 Use of ETO at Ports of Entry

Fumigation with ETO as a quarantine treatment for cargo contaminated with snails or certain plant disease organisms is required by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture (USDA). These tarpaulin fumigations, which are carried out under the supervision of a USDA Quarantine Inspector, may be conducted at any port of entry into the United States where these normative pests are identified (USDA 1976; Havel 1980).

MITRE contacted contract fumigators at eight ports of entry in five states and obtained information on their ETO operations. These contract fumigators perform the ETO fumigation and USDA inspectors supervise and monitor the fumigation operation (Venech 1980).

6.9.2 Control Measures

ETO fumigation at ports of entry is conducted without the use of a chamber.* Tarpaulin fumigation is carried out by professional fumigation firms whose employees follow several work practices to control worker exposure to ETO.** These procedures, which are detailed in Appendix C (Table C-9), are summarized below.

- Fumigators at five ports of entry reported that they follow the tarpaulin fumigation procedures specified in the U.S. Department of Agriculture Plant Protection and Quarantine Programs Treatment Manual. Fumigators at the other three sites did not report compliance with the USDA procedures; however, these fumigations are supervised by USDA inspectors and it can be assumed that these three fumigators follow the procedures as well.

- Fumigation is conducted outdoors at five of the ports of entry sites and indoors at three sites (in a hangar, maintenance garage, and empty warehouse, respectively) which allow the fumigation to take place away from general work areas.

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*ETO tarpaulin fumigation at ports of entry is described in Section 2.2.3.

**Commercial pest control operators are certified pesticide applicators; however, only one certified applicator is required to supervise the pesticide applications of one firm (Eliades 1980). It is assumed that the individual operators at these firms have been trained in fumigation procedures.

- Placards and guards to warn potential passersby of the fumigation operation are posted at three of the ports of entry sites.

- Fumigators at seven ports of entry provide gas masks or self-contained breathing apparatus to operators for use at their discretion.

- Fumigators at seven ports of entry transport ETO-treated material by forklift.

6.9.3 Monitoring

Only one of the fumigators reported the use of monitoring equipment to determine ambient ETO concentrations in the workplace. This fumigator reported use of a combustible gas detector to monitor ETO concentrations in the empty garage after the tarpaulin is removed. Additional information was not reported (Gervasoni 1980).

No situations of potential worker exposure to ETO were identified by the respondents at this site.

6.10 Spices, Seasonings, and Black Walnut Meats Industry

6.10.1 Use of ETO by the Spice Industry

ETO fumigation is used by spice manufacturers and processors as a disinfectant to control pathogenic organisms that infect spices and to reduce microbial growth on imported spices (Marsh 1979).

Approximately 27 spice processing companies were requested by the American Spice Trade Association to provide information regarding control measures. Of these, responses were received from 21 companies. The information obtained from these 21 facilities is detailed in Appendix C (Table C-10) and discussed below.

6.10.2 Situations Associated with Potential Worker Exposure

Situations associated with potential worker exposure to ETO at spice industry facilities may result from a number of work practices and workplace design features.

- At three spice industry firms sterilizer operators unload treated materials from the sterilizer immediately after opening the chamber door.*
- Sterilizer operators enter the chamber to unload treated materials at eight spice industry facilities;** however, at several of these facilities, workers are required to wear respiratory protection equipment.
- Employees may be exposed to ETO from offgassing from treated goods at 16 facilities. At these facilities, treated materials are aerated in the general warehouse in warehouse areas specially designated as aeration areas but lacking special ventilation, or in warehouse aeration areas that are vented to the atmosphere. These facilities did not report whether personnel not involved in the sterilization process were routed around or away from the aerating material, or if these areas were near walkways available for general use.

6.10.3 Control Measures

Sterilizer operators at the 21 spice industry facilities use ETO sterilization equipment equipped with engineering features or follow specific work practices to control worker exposure to ETO.

- An automatic leak detection system which monitors the vacuum or pressure levels in the chamber and alerts the operator of abnormal equipment operations has been installed in the chamber at one spice industry facility.

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*It should be noted that various types of chamber evacuation systems which may decrease ETO concentrations released to the workplace upon opening the chamber door are utilized at two of these three facilities.

**Five facilities did not report whether their sterilizer operators enter the chamber to unload the treated materials.

- Area monitoring systems are used by two facilities. Two facilities use a Honeywell Gas/Vapor Detector for Freon 12 to monitor gas levels in the ETO work area. The detector is equipped with a visual and audible alarm system and is located adjacent to the chamber. Four other facilities reported that their chambers are equipped with an alarm monitoring system, but did not provide further details.

- Sterilization chambers at 18 spice industry facilities are equipped with multiple post-vacuums or air washes to facilitate evacuation of gases from the chamber.

- Sterilizers at two facilities (among 12 that exhaust spent gas to the drain) are equipped with a liquid/gas separator.

- A remote controlled door opening switch has been installed into the chamber operating equipment at one spice industry facility.

- General area ventilation systems are used at 16 spice industry facilities.

- Access to the ETO sterilization area is restricted or the ETO work area is isolated from other areas in the workplace at 16 spice industry facilities.

- Sterilizer operators at 20 spice industry facilities have received training in ETO sterilization procedures either from the chamber manufacturer or under "in-house" supervision.

- The sterilizer door is left open for a short period at the completion of the sterilization cycle (to permit residual ETO gas to dissipate) before the treated materials are unloaded from the chamber at 18 facilities.

- Material handling equipment, such as forklifts, are used to transfer treated materials from the sterilizer to aeration areas at 16 spice industry facilities.

- A regularly scheduled program of equipment inspection and maintenance is conducted either by the chamber manufacturer or by in-house maintenance personnel at 19 facilities.

- Personal protective equipment, including respirators, gloves, and goggles, is worn by operators while operating the chamber or while unloading or handling ETO treated materials at 12 facilities.

6.10.4 Monitoring

Monitoring to determine ambient ETO concentrations in the workplace has been conducted at 12 spice industry facilities.

- Three facilities have conducted monitoring with Wilks-Miran infrared gas analyzers. One of these three facilities reported using a Wilks-Miran 101 gas analyzer to monitor all phases of the ETO operation cycle. In response to the data obtained from this monitoring, this facility reported increasing the ventilation over the chamber doors, instituting a 30-minute delay between opening the chamber door and unloading the treated materials, and requiring the worker to wear a respirator if entry to the chamber is required during removal of the treated materials. This facility also reported that two subsequent monitorings indicated that worker exposure to ETO has been reduced to 12.6 ppm and 17.4 ppm, respectively, over an 8-hour Time Weighted Average. At the other two facilities, monitoring was either reported to be in progress or indicated that ETO levels in the sterilizer area were below 50 ppm.

- Four facilities conducted monitoring in the workplace following the procedures of NIOSH Analytical Method S286.* In response to the results obtained from monitoring, two of these facilities have made changes in their operating procedures and sterilization equipment. At one facility a 30-minute delay between opening the chamber door and unloading the chamber was instituted. At the second facility (which has also conducted monitoring of the workplace and storage areas using an infrared gas analyzer) a 15-minute air wash (with the chamber door open) was implemented. The other two facilities using the NIOSH method have not made changes to their ETO sterilization operations, but did report obtaining ETO levels of 1.6 ppm and 0.29 ppm as an 8-hour Time Weighted Average, respectively.

- Five of these facilities reported that they had performed monitoring of the workplace and that ETO concentrations were determined to be "safe" or within the OSHA standard of 50 ppm (8-hour Time Weighted Average).

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*This method involves adsorption of the ETO on charcoal collection tubes, and gas chromatographic determination of ETO levels following desorption with carbon disulfide (Glaser 1977).

6.11 Cosmetics Industries

6.11.1 Use of ETO By the Cosmetics Industry

Fumigation with ETO is the most frequently used method for reducing microbial levels in a wide variety of cosmetic ingredients and hardware items. The widespread use of ETO is a recent development. Since 1970, ETO treatment has increased in response to concern expressed by the U.S. Food and Drug Administration (FDA) regarding the health hazard potential of contaminated cosmetic products (Butcher and Goldgraben 1980).

In Preliminary Benefits Analysis of Ethylene Oxide in the Cosmetics Industry (Butcher and Goldgraben 1980), MITRE reported that ETO treatment of cosmetic products is performed almost exclusively by contract sterilizers. Micro-Biotrol Company, a Division of Griffith Laboratories, fumigates 80 to 84 percent of the cosmetic raw materials and 100 percent of the hardware items used by the cosmetics industry (Butcher and Goldgraben, 1980). Micro-Biotrol Company was contacted and requested to supply additional information on its ETO cosmetics fumigation operations for this report. The information supplied by Micro-Biotrol regarding measures implemented to control and monitor worker exposure to ETO at its five ETO treatment facilities is detailed in Appendic C (Table C-11) and discussed below.*

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*This information, with the exception of data on the size of ETO sterilizers and the total number of operators, was reported to be applicable to all of the five facilities operated by Micro-Biotrol.

6.11.2 Situations Associated with Potential Worker Exposure

The only situation associated with potential worker exposure to ETO occurs when the sterilizer operators enter the sterilizer to retrieve ETO-treated materials; however, the degree and duration of this potential exposure may be minimal due to the material handling equipment used to remove the treated materials from the chamber and the equipment and workplace design control measures instituted at these facilities.

6.11.3 Control Measures

Sterilizer operators at Micro-Biotrol use ETO sterilization equipment designed with certain engineering features, work in areas with proper workplace designs, and follow work practices to control worker exposure to ETO.

- Chambers at Micro-Biotrol facilities are equipped to create multiple post-vacuums at the end of the sterilization cycle. One vacuum is typically employed; however, a second full vacuum is created prior to opening of the chamber door if at least one hour has elapsed since the completion of the sterilization cycle.

- The chamber circulation systems have been modified to operate during chamber unloading to facilitate dilution of residual ETO in the rear of the chamber where air circulation may be normally limited.

- Liquid/gas separators are installed in the chamber vent system to reduce the amount of ETO which is released at the drain during the exhaust phase of the sterilization cycle.

- Ventilation of the workplace is accomplished through various techniques at these facilities. Mechanical ventilation (fans) is used to direct the airflow towards the ETO work area from non-ETO areas and fans located above each chamber are used to direct airflow away from the worker and facilitate dispersion of the ETO as it escapes from the chamber.

In addition, the storage rooms (aeration areas) are equipped with air circulation systems in which fresh air is introduced at the ceiling level and vented at the floor level.

- Access to the ETO sterilization area at each facility is restricted to authorized personnel.
- Operators receive a three month in-house training program on ETO procedures, instruction in hazard identification, and procedures to be followed in emergency situations.
- Sterilizer operators leave the chamber door open for at least five minutes before unloading the ETO-treated materials.
- Operators use battery powered transports or hand pallet movers to transfer pallets (containing treated materials) from the sterilizer to specially designated aeration areas in the facility.
- ETO sterilization equipment is serviced twice annually by in-house personnel. In addition, Micro-Biotrol has instituted a system of record-keeping for inspection and maintenance.

6.11.4 Monitoring

Micro-Biotrol has performed monitoring using a Wilks-Miran 101 Gas Analyzer and a gas chromatograph (presumably in conjunction with personnel monitoring samples). Based on this monitoring, Micro-Biotrol reported that its workers were exposed to less than 50 ppm, as an 8-hour time-weighted average. Additional information was not reported.

6.12 Dairy Packaging Industry

The dairy packaging industry uses ETO to sterilize only those packages that are required for long shelf-life dairy products, such as coffee cream, whipping cream, or half and half, to prevent contamination of the dairy product. Presterilization of the packaging materials for these ultrapasteurized dairy products extends the shelf-life of those products from less than 10 days to between 45 and 60 days (Smith 1980a).

ETO sterilization of packaging materials is not within the normal operating practices of most dairies or paperboard manufacturers; therefore, these materials are, with few exceptions, treated by contract sterilizers (Johnson 1980). Approximately 77 percent of these sterilized packaging materials are treated by Micro-Biotrol Company (Smith 1980b).

Micro-Biotrol sterilizes these dairy packaging materials in the same facilities that sterilize cosmetic raw materials and hardware items (Smith 1980a); therefore, the measures used by Micro-Biotrol to control and monitor worker exposure to ETO are the same for dairy packaging materials as they are for cosmetic raw materials and hardware items. This information is discussed in Section 6.11 above and detailed in Appendix C (Table C-11).

7.0 CONCLUSIONS

- ETO sterilization/fumigation is most typically conducted in a vacuum chamber in which a vacuum system is used to remove a portion of the ETO present in the chamber prior to the conclusion of the treatment cycle. Such chambers are the most common type of equipment in use at 10 of the 12 sites of interest.

- Information regarding sources and extent of worker exposure is primarily derived from hospital facilities using vacuum chambers. Little information is currently available regarding worker exposure at other sites and at facilities in which other types of containment equipment are used.

- Three categories of workers may be exposed to ETO: chamber operators, maintenance personnel, and other workers stationed in the general vicinity of the ETO treatment operation. Chamber operators may be exposed to ETO while unloading the chamber and in the course of handling treated goods; maintenance personnel may be exposed while performing routine operations such as replacing emptied sterilant cylinders or, less frequently, while performing repair work resulting from equipment breakdown or system malfunction. ETO released from these exposure events as well as ETO releases from other sources such as leaks may also result in passive exposure to these and other workers who are not directly involved in the treatment process.

- Patterns of worker exposure to ETO are characterized by short periods of exposure to relatively high concentrations of ETO; however, available information for both hospital and industrial users indicates that 8-hour time-weighted average exposures are typically at or below current OSHA standards (50 ppm TWA).

- Worker exposure to ETO can be reduced to levels substantially below current OSHA standards by the implementation of currently available control measures.

- Measures currently available to reduce worker exposure generally follow accepted industrial hygiene practices. Such measures include engineering modifications to the equipment intended to prevent or minimize ETO releases to the workplace, workplace design considerations intended to dilute or remove ETO once released and to isolate sources of exposure, and work practices intended to minimize the duration of worker exposure and, in some instances, to isolate the worker from exposure sources.

- Manufacturers of sterilization equipment have developed engineering modifications to control and minimize ETO release. To date, the primary focus has been directed towards improving the effectiveness of chamber evacuation systems, particularly for small and intermediate sized chambers. While several alternative approaches have been developed, the continuous purge feature offered by 3M appears to be the most effective method as it substantially reduces both the amount of ETO released when the chamber door is initially opened and the amount subsequently offgassed from treated goods. This approach, in effect, permits preliminary aeration to be conducted in the sterilization chamber.

- Engineering controls for large industrial chambers have primarily been directed at methods of ventilating the chamber after the door is opened by forcing air from the workplace into and through the chamber. This serves to minimize the extent of ETO release to the workplace and, when operated during the unloading process, provides sufficient airflow over the operator to control exposure to offgassing ETO.

- Utilization of a local exhaust system appears to be the most generally applicable control measure, as it may be used to control a number of discrete sources of ETO release, both routine and non-routine.

- Health care and industrial ETO users (including contract sterilizers and the medical products, spices, cosmetics, and dairy packaging industries) have been most likely to implement control measures. In addition, some industrial users have been instrumental in developing innovative engineering controls. ETO users at other site have made little effort to assess and control worker exposure to ETO due, in part, to limited information regarding the potential health effects associated with such exposure. Many ETO users at "minor" sites (including libraries, museums, research laboratories, the beekeeping industry, and high containment research laboratories) have reported that they were unaware of any health hazards associated with ETO use. Where control measures have been implemented, these were instituted primarily for other purposes and incidentally serve to control worker exposure to ETO.

- Some ETO users have implemented controls sufficient to comply with current OSHA standards for worker exposure may be postponing implementation of additional measures in anticipation of downward revision of these standards.

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APPENDIX A

SITE VISITS CONDUCTED

APPENDIX A

SITE VISITS CONDUCTED

Site	Facility
Health Care	Doctor's Hospital of Prince George's County Lanham, Maryland
	Genessee Hospital Rochester, New York
	Walter Reed Army Medical Center Washington, D.C.
Medical Products Industry	Cheshire Laboratories, Inc. Piscataway, New Jersey
	Med-Surg Industries, Inc. Rockville, Maryland
	Sterilization Services of Georgia (Vacudyne/Altair) Atlanta, Georgia
Libraries	Library of Congress Washington, D.C.
	National Archives Washington, D.C.
Museums	National Museum of History and Technology Washington, D.C.
	National Museum of Natural History Washington, D.C.
Research Laboratories	Frederick Cancer Research Center Frederick, Maryland
	National Institutes of Health Bethesda, Maryland

APPENDIX A (CONCLUDED)

Beekeeping Industry	Maryland Department of Agriculture Beltsville, Maryland
High Containment Research Laboratories	Plum Island Animal Disease Center Greenport, New York
Animal and Plant Service Quarantine at Ports of Entry	U.S. Department of Agriculture Dover Air Force Base Dover, Delaware
Equipment Manufacturers	American Sterilizer Company (AMSCO) Erie, Pennsylvania Castle-Sybron Corporation Rochester, New York 3M Corporation ST. Paul, Minnesota

APPENDIX B

EVALUATION OF WORKER EXPOSURE AND AMBIENT ETO CONCENTRATIONS AT A HOSPITAL CENTRAL SUPPLY FACILITY

THE UNIVERSITY OF ARIZONA
HEALTH SCIENCES CENTER
TUCSON, ARIZONA 85724

UNIVERSITY HOSPITAL
PHARMACY & SUPPLY DEPARTMENT

17 September 1980

Renee Goldgraben
Toxic Substances Control
The MITRE Corporation/Metrek Division
1820 Dolley Madison Boulevard
McLean, Virginia 22102

Dear Renee,

I enjoyed meeting and talking with you in Denver. Dr. Samuels and I are very glad to have the opportunity to help you and thus to help the EPA in data gathering.

Enclosed please find more information about our two major studies on ethylene oxide control. I didn't locate all that we had done, but I have included what I could find that wasn't in the published material. The pages are divided into two sections. A brief explanation of the enclosed material may help you, so here goes.

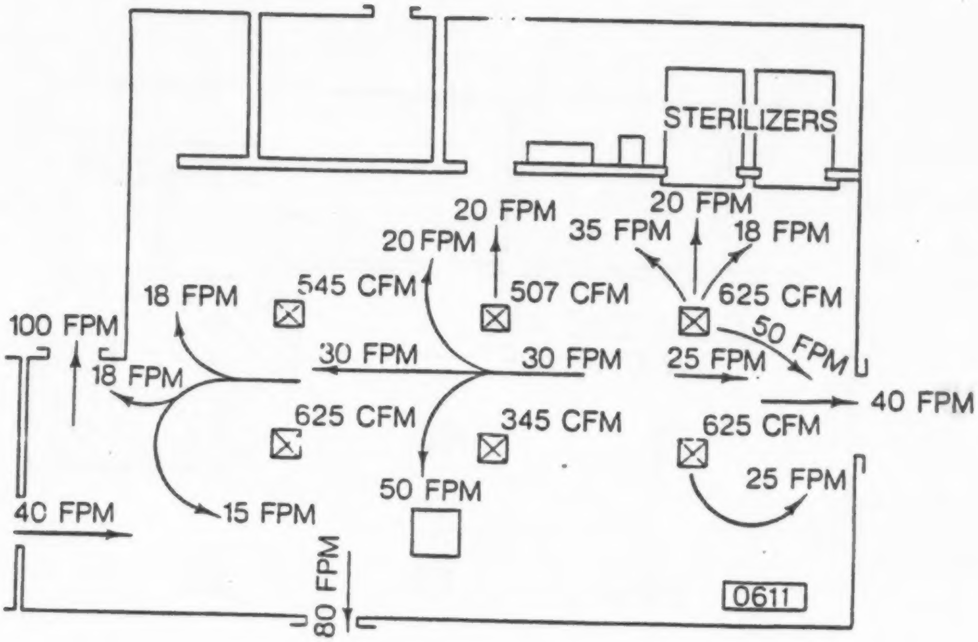
The first study in 1978 was to look at the existing situation here and see what could be done to improve it. Page 1 shows the existing air flow and p.2 shows how it is affected by the sterilizers. Page 3 shows how the room was"divided" into 10 sections for area monitor sampling. The large aeration cabinet was monitored near the exhaust vent and the results are on p.4. A cold cycle was monitored (p.5) and another "process sample" was taken (p.6) before we began the area sampling. Each grid was monitored for a full day with events noted. Pages 7-18 show the results of this monitoring with the minute-by-minute readings. Pages 19-25 show several of these grids plotted out. I couldn't find the others. A summary with the 8-hour TWA for each grid is on p.26.

The second study in 1979 was designed to examine the effects of local exhaust hoods (3M - models 200 & 400B), cycle purge modifications (Castle), and new sterilizer improvements (3M - M400B). Data was collected from the locations shown on p. 27. Charcoal tubes were used to collect air samples at the five locations. The loads were run simultaneously in each sterilizer but because of the length of the cycles they came out about an hour apart. Each test situation was duplicated and results analyzed for sililarity. Results for the 3M model 200 are on pages 28-31, for the 3M 400B on pages 32-35, and pages 36-39 for the Castle sterilizer. These results with each run shown are all on p.40 as received from the laboratory. A graph of the 400B results is on p.41. Pages 42-49 show the breakdown of the infra-red analyzer data collected on the 400B. I couldn't find the other two sets. The method used to find the TWA's is shown there also.

I trust that this material will be helpful to you. I am sure that when Dr. Samuels returns in October we can send you more data if you would like.

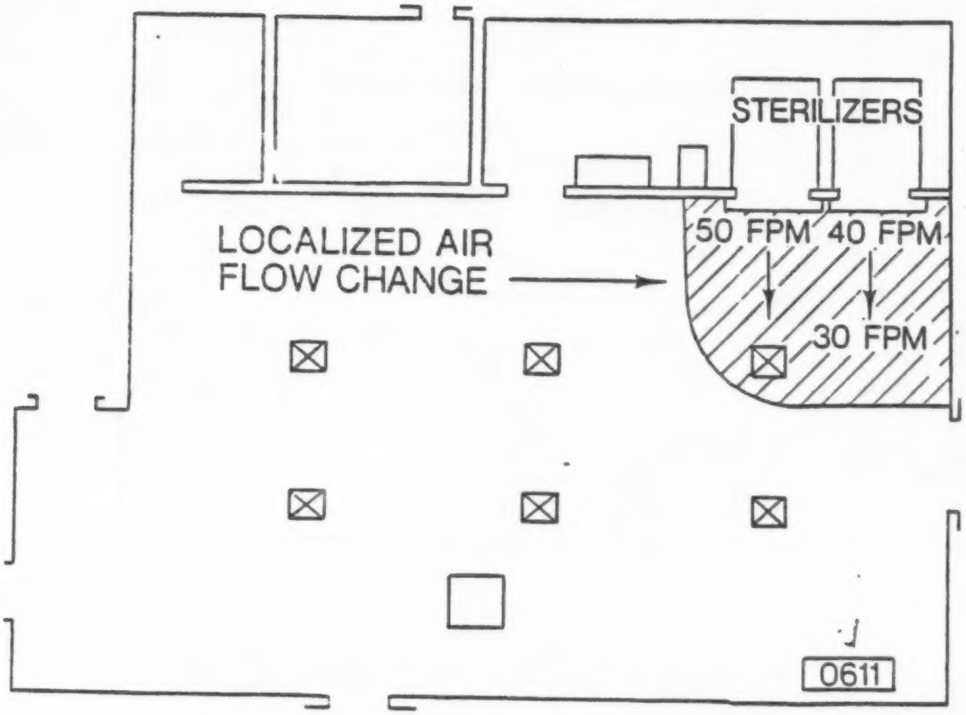
Thanks again for your interest in our work. I hope that we will be able to do much more in the near future. I look forward to hearing from you soon.

Sincerely,
Randy Corn
Randy Corn
Supervisor
Sterilization



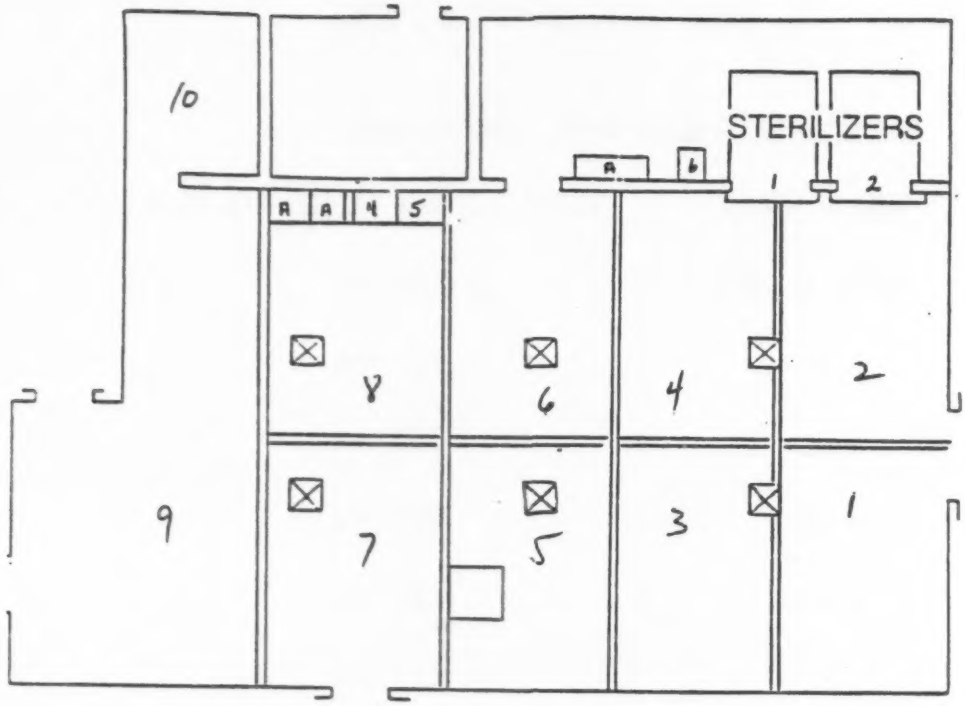
OPERATION WITH STERILIZER

DOORS CLOSED



STERILIZER DOORS OPENED

UPON COMPLETION OF CYCLE


A
b
STERILIZERS
A
A

LARGE AERATION CABINET VENT

DETECTOR 12 INCHES FROM EXHAUST VENT

PREFAN STAGE	RANGE 1.5 PPM TO 500 PPM (6 MIN)
INITIAL SURGE	> 1200 PPM
1 MIN	720 PPM
2 MIN	360 PPM
3 MIN	240 PPM
5 MIN	168 PPM
15 MIN	120 PPM
25 MIN	108 PPM
30 MIN	108 PPM

SMALL STERILIZER

LOAD - BAG OF GLASS SYRINGES - COLD CYCLE

DETECTOR LOCATED AT BREATHING ZONE HEIGHT; 12 INCHES FROM CABINET TO THE LEFT OF THE DOOR.

INITIAL OPENING	385 PPM.	
1 MIN	120 PPM	
2 MIN	96 PPM	
3 MIN	24 PPM	
5 MIN	0 PPM	
8 MIN	24 PPM	(IN AERATION CABINET - POSSIBLE SURGE FROM CABINET)

SMALL STERILIZER AND SMALL AERATOR

LOCATION: CENTER OF 2 MODEL 200'S - 28 INCHES;
APPROXIMATELY 60 INCHES FROM AERATOR

START: 7:00 AM

7:00 AM - 0 PPM
9:40 AM - 0 PPM (START CYCLE #4 & #5)
10:50 AM - 5 PPM (CYCLE END - DOOR OPENED)
10:55 AM - 600 PPM
10:56 AM - 864 PPM
10:57 AM - 480 PPM
10:58 AM - 220 PPM
10:59 AM - 100 PPM
11:00 AM - 75 PPM
11:15 AM - 10 PPM
12:00 - 5 PPM
12:50 PM - 2.5 PPM (CYCLE ENDS, #4 & #5 OPENED)
12:50 PM - 410 PPM
1:00 PM - 50 PPM
1:01 PM - 625 PPM
1:05 PM - 105 PPM
1:10 PM - 5 PPM

PROCESS SAMPLE (see graph)

GRID 1

LANDMARKS: 27 FT FROM #5
21 FT FROM #2
22 FT FROM LARGE AERATOR
30 FT FROM SMALL AERATOR
29 FT FROM #4

START: 7:15 AM

7:15 AM - 0 PPM
8:05 AM - 0 PPM (#5 OPENED - LEFT CLOSED OVERNIGHT)
8:08 AM - 60 PPM
8:13 AM - 75 PPM
8:15 AM - 10 PPM
8:18 AM - 20 PPM (ITEM PLACED IN LG AERATOR)
8:20 AM - 20 PPM
8:30 AM - 0 PPM
12:35 PM - 30 PPM (LG CART CONTAINING PREVIOUSLY GASSED ITEM HELD IN QUARANTINE MOVED AROUND SENSOR)
12:40 PM - 5 PPM
2:50 PM - 0 PPM (#4 OPENED)
2:55 PM - 5 PPM
3:00 PM - 0 PPM
3:40 PM - 0 PPM

GRID

LANDMARKS: 19 FT FROM #5
10 FT FROM #2
24 FT FROM SMALL AERATOR
15 FT FROM LARGE AERATOR
21 FT FROM #4

START: 4:15 PM

4:20 PM - 0 PPM (OPENED #4)
4:23 PM - 20 PPM
4:24 PM - 40 PPM
4:25 PM - 30 PPM
4:26 PM - 20 PPM
4:28 PM - 10 PPM
4:30 PM - 0 PPM
10:10 PM - 0 PPM
10:14 PM - 30 PPM (OPENED #2)
10:15 PM - 250 PPM
10:16 PM - 80 PPM
10:17 PM - 60 PPM
10:18 PM - 40 PPM
10:19 PM - 30 PPM
10:20 PM - 20 PPM
10:21 PM - 15 PPM
10:22 PM - 10 PPM
10:25 PM - 0 PPM

GRID 2 (WHEAT)

LANDMARKS: 19 FT FROM #5
10 FT FROM #2
24 FT FROM SMALL AERATOR
15 FT FROM LARGE AERATOR
21 FT FROM #4

START: 7:45 AM

8:00 AM - 0 PPM
10:35 AM - 0 PPM (#4 & #5 OPENED)
10:40 AM - 25 PPM
10:41 AM - 45 PPM
10:42 AM - 40 PPM
10:43 AM - 40 PPM
10:44 AM - 25 PPM
10:45 AM - 25 PPM
10:46 AM - 20 PPM
10:50 AM - 5 PPM
10:55 AM - 0 PPM
4:00 PM - 0 PPM
4:05 PM - 50 PPM
4:10 PM - 0 PPM

FIRST
SHIFT

GRID 2 - REPEAT (CONT'D)

9:30 PM - 0 PPM (#2 OPENED)
9:34 PM - 200 PPM
9:35 PM - 325 PPM
9:36 PM - 150 PPM
9:40 PM - 25 PPM
9:50 PM - 0 PPM

SECOND
SHIFT

GRID 3

LANDMARKS: 22 FT FROM #5
24 FT FROM #2
20 FT FROM LARGE AERATOR
27 FT FROM SMALL AERATOR
24 FT FROM #4

START: 9:40 AM

11:28 AM - 0 PPM (#2 OPENED)
11:29 AM - 0 PPM
11:30 AM - 15 PPM
11:31 AM - 30 PPM
11:32 AM - 45 PPM
11:33 AM - 55 PPM
11:34 AM - 55 PPM
11:35 AM - 50 PPM
11:36 AM - 50 PPM
11:37 AM - 167 PPM
11:38 AM - 100 PPM
11:39 AM - 85 PPM
11:40 AM - 70 PPM
11:41 AM - 60 PPM
11:42 AM - 50 PPM
11:43 AM - 40 PPM
11:44 AM - 30 PPM
11:45 AM - 25 PPM
11:46 AM - 25 PPM
11:47 AM - 20 PPM
11:48 AM - 25 PPM
11:49 AM - 20 PPM
11:50 AM - 15 PPM
11:51 AM - 10 PPM
11:55 AM - 5 PPM
12:00 - 0 PPM
2:20 PM - 0 PPM
2:24 PM - 0 PPM (#4 & #5 OPENED)
2:25 PM - 20 PPM
2:26 PM - 55 PPM
2:27 PM - 60 PPM
2:28 PM - 25 PPM
2:29 PM - 25 PPM
2:30 PM - 20 PPM
2:31 PM - 20 PPM
2:32 PM - 15 PPM
2:33 PM - 15 PPM
2:34 PM - 10 PPM
2:35 PM - 10 PPM
2:40 PM - 0 PPM

GRID 4

LANDMARKS: 14 FT FROM #5
15 FT FROM #2
17 FT FROM SMALL AERATOR
10 FT FROM LARGE AERATOR
16 FT FROM #4

START: 7:45 AM

1:35 PM - 0 PPM (#4 OUT)
1:39 PM - 5 PPM
1:40 PM - 35 PPM
1:41 PM - 25 PPM
1:42 PM - 20 PPM
1:43 PM - 15 PPM
1:44 PM - 10 PPM
1:45 PM - 5 PPM
1:46 PM - 0 PPM

GRID [illegible]

LANDMARKS: 21 FT FROM #5
42 FT FROM #2
22 FT FROM SMALL AERATOR
33 FT FROM LARGE AERATOR

START: 7:20 AM

2:05 PM - 0 PPM (TAKE OUT #4)
2:07 PM - 10 PPM
2:08 PM - 20 PPM
2:09 PM - 18 PPM
2:10 PM - 10 PPM
2:11 PM - 10 PPM
2:12 PM - 5 PPM
2:13 PM - 0 PPM
3:05 PM - 0 PPM (#5 OUT)
3:07 PM - 5 PPM
3:08 PM - 25 PPM
3:09 PM - 25 PPM
3:10 PM - 20 PPM
3:11 PM - 15 PPM
3:12 PM - 10 PPM
3:13 PM - 5 PPM
3:14 PM - 5 PPM
3:15 PM - 5 PPM
3:20 PM - 0 PPM

GRID

LANDMARKS: 9 FT FROM #5
12 FT FROM SMALL AERATOR
15 FT FROM LARGE AERATOR
11 FT FROM #4

START: 7:25 AM

10:50 AM - 0 PPM (#4 OPENED)
10:53 AM - 155 PPM
10:54 AM - 150 PPM
10:55 AM - 125 PPM
10:56 AM - 80 PPM
10:57 AM - 60 PPM
10:58 AM - 40 PPM
10:59 AM - 25 PPM
11:00 AM - 15 PPM
11:01 AM - 15 PPM
11:02 AM - 10 PPM
11:03 AM - 10 PPM
11:04 AM - 0 PPM
12:50 PM - 0 PPM
12:55 PM - 0 PPM (#5 OPENED)
12:56 PM - 0 PPM
12:57 PM - 70 PPM
12:58 PM - 35 PPM
12:59 PM - 20 PPM
1:00 PM - 15 PPM
1:01 PM - 15 PPM
1:02 PM - 10 PPM
1:03 PM - 10 PPM
1:04 PM - 15 PPM
1:05 PM - 5 PPM
1:10 PM - 0 PPM
2:05 PM - 0 PPM (#5 OPENED)
2:06 PM - 15 PPM
2:07 PM - 175 PPM
2:08 PM - 125 PPM
2:09 PM - 50 PPM
2:10 PM - 25 PPM
2:11 PM - 20 PPM
2:12 PM - 20 PPM
2:13 PM - 40 PPM
2:14 PM - 15 PPM
2:15 PM - 15 PPM
2:20 PM - 15 PPM
2:25 PM - 0 PPM

GRID

LANDMARKS: 26 FT FROM #5
40 FT FROM #2
24 FT FROM #4
23 FT FROM SMALL AERATOR
30 FT FROM LARGE AERATOR

START 7:30 AM

9:10 AM - 0 PPM (#4 OPENED)
9:14 AM - 5 PPM
9:15 AM - 60 PPM
9:16 AM - 85 PPM
9:17 AM - 80 PPM
9:20 AM - 40 PPM
9:25 AM - 15 PPM
9:30 AM - 0 PPM
12:35 PM - 0 PPM
12:37 PM - 0 PPM (#4 & #5 OPENED)
12:40 PM - 20 PPM
12:41 PM - 30 PPM
12:44 PM - 30 PPM
12:45 PM - 20 PPM
12:50 PM - 10 PPM
1:00 PM - 0 PPM
3:30 PM - 0 PPM

GRID 8

LANDMARKS: 10 FT FROM #4
10 FT FROM #5
6 FT FROM 8M AERATION CABINET

START: 7:00 AM

7:00 AM - 0 PPM
9:00 AM - 0 PPM
9:40 AM - 155 PPM
9:42 AM - 250 PPM
9:45 AM - 90 PPM
9:50 AM - 25 PPM
10:00 AM - 20 PPM
10:30 AM - 10 PPM
11:00 AM - 10 PPM
11:30 AM - 0 PPM

1ST PEAK - #4 OPENED

2ND PEAK - #5 OPENED

9 PLASTIC 1000 ML GRADUATES
PLACED ON TOP OF AERATOR
DUE TO LACK OF ROOM
REMOVED 11:00 AM

GRID 8 (CONT'D)

11:50 AM - 0 PPM
11:51 AM - 75 PPM
11:52 AM - 150 PPM
11:53 AM - 195 PPM
11:55 AM - 75 PPM
12:00 - 20 PPM
12:05 PM - 7.5 PPM
12:20 PM - 0 PPM

1ST PEAK - #5 OPENED

2ND PEAK - #4 OPENED

SMALL LOAD CONTAINING 2 TRANSDUCERS AND 2 TUBINGS

2:05 PM - 0 PPM
2:06 PM - 65 PPM
2:10 PM - 10 PPM
2:21 PM - 15 PPM
2:30 PM - 5 PPM
3:00 PM - 0 PPM

#5 OPENED

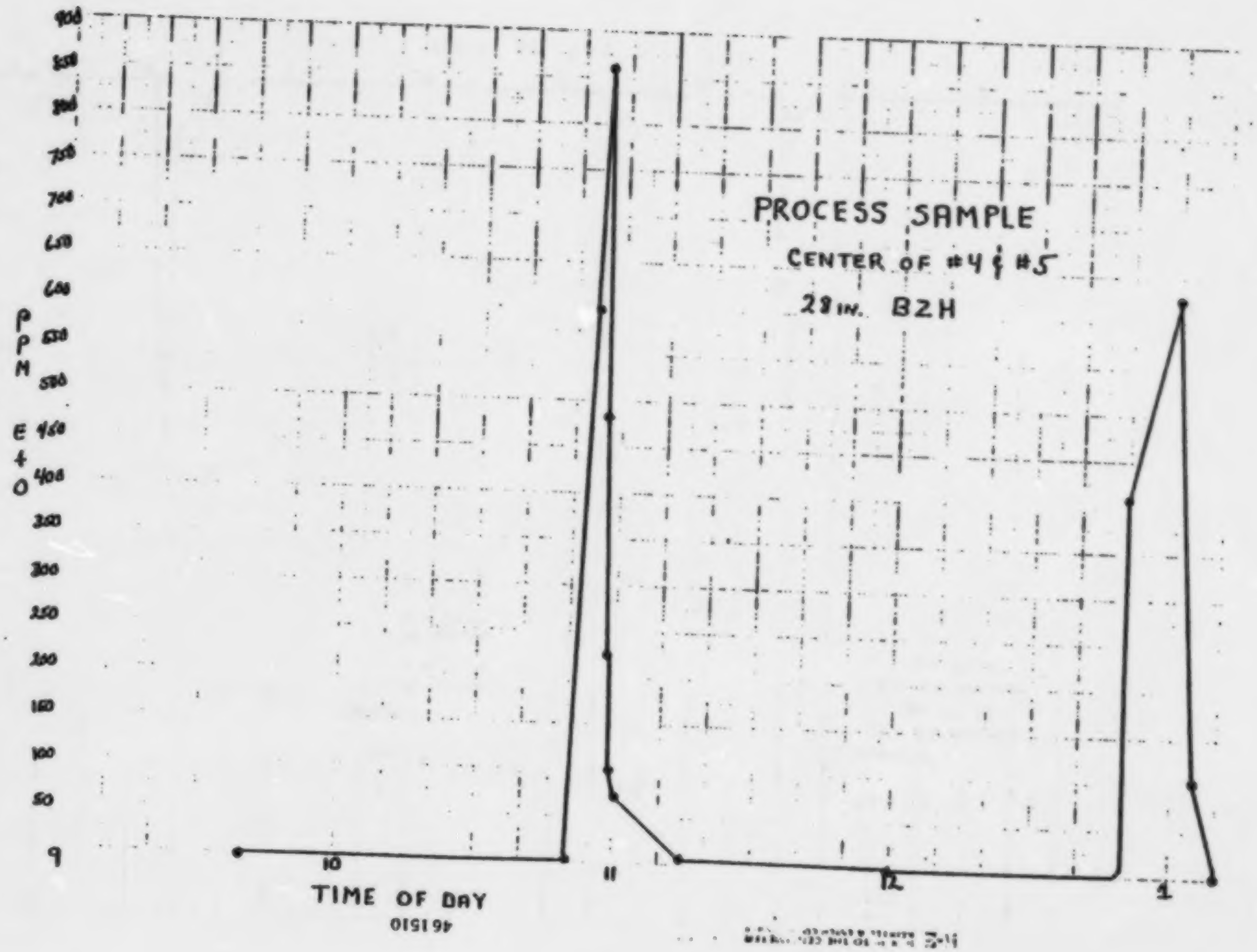
SEVERAL ITEMS SORTED AND PLACED ON TOP TAKEN TO LARGE AERATOR

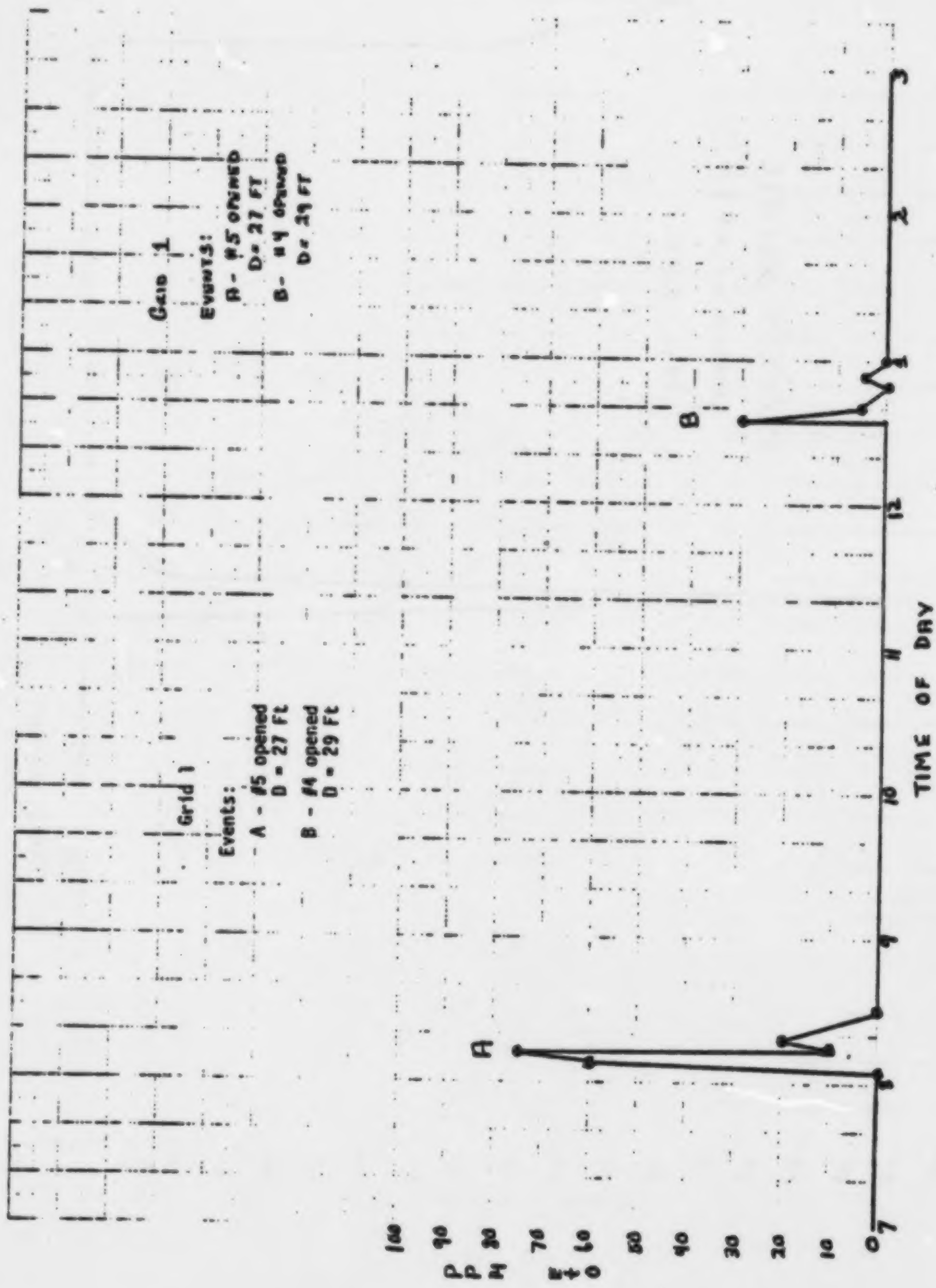
GRID [illegible]

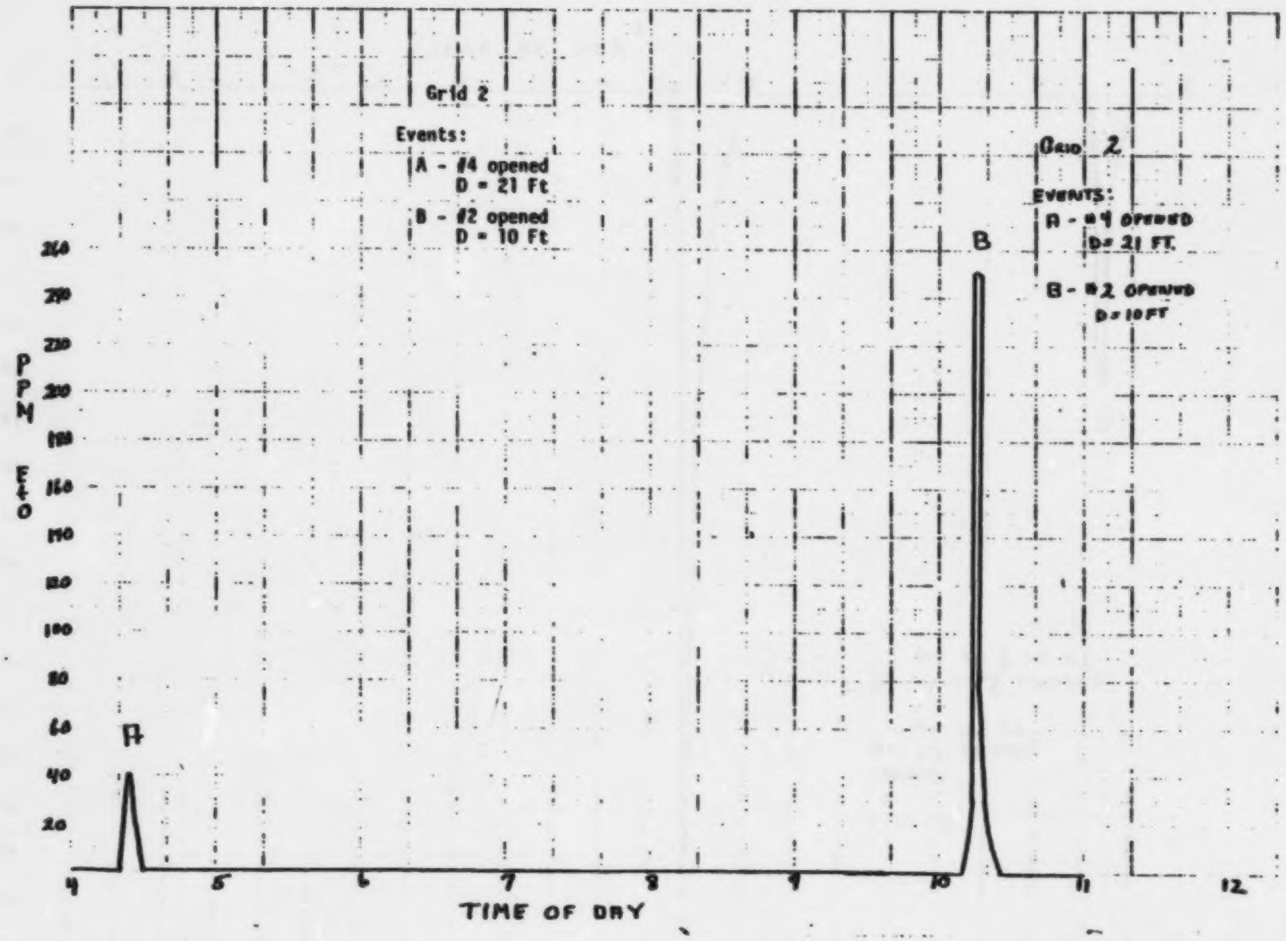
LANDMARKS: 30 FT FROM #5
45 FT FROM #2
27 FT FROM SMALL AERATOR
34 FT FROM LARGE AERATOR
28 FT FROM #4

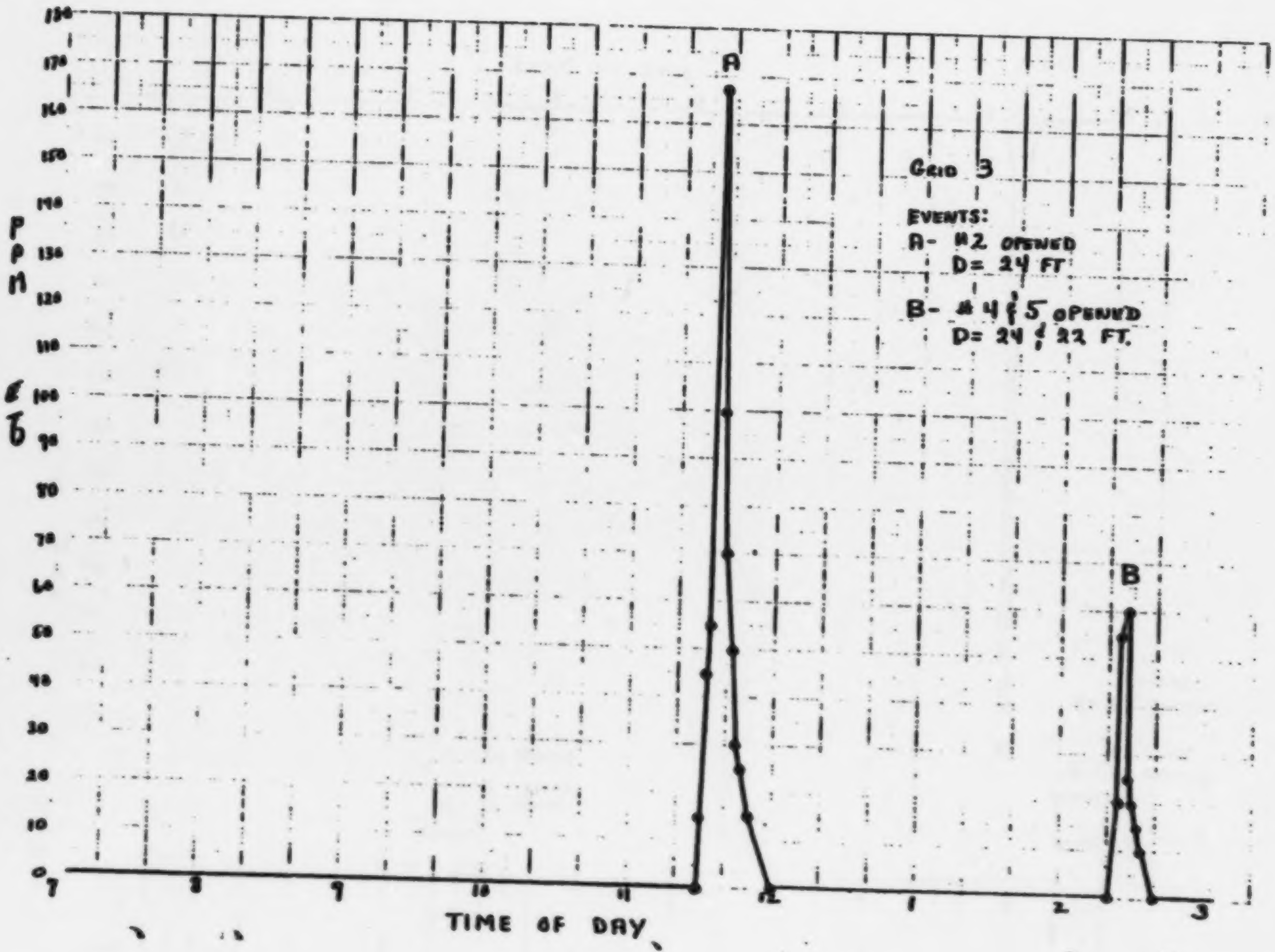
START: 8:00 AM

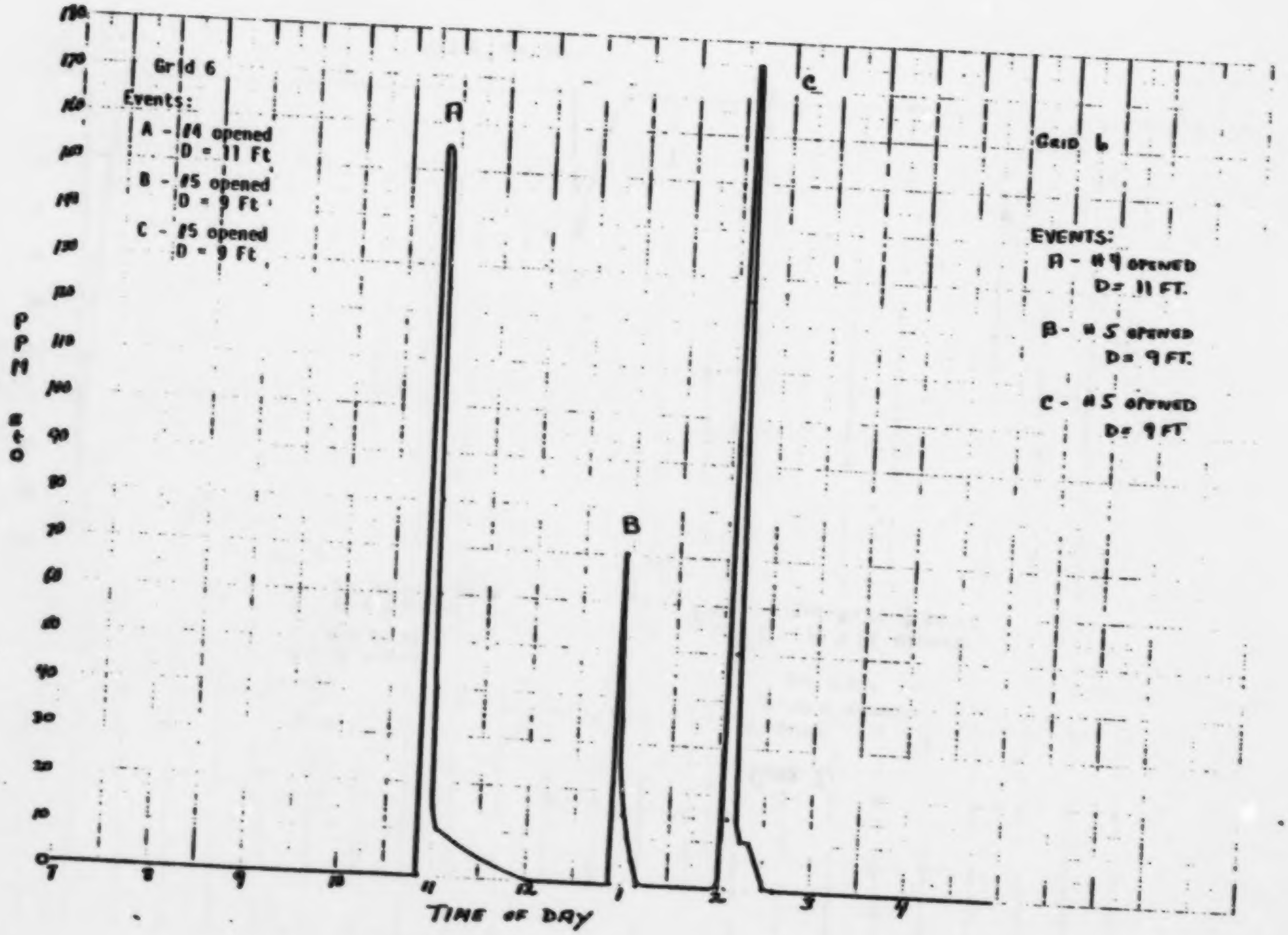
9:50 AM - 0 PPM (#4 OPENED)
9:54 AM - 3 PPM
9:55 AM - 30 PPM
9:56 AM - 40 PPM
9:57 AM - 42 PPM
9:58 AM - 33 PPM
10:00 AM - 15 PPM
10:05 AM - 5 PPM
10:10 AM - 0 PPM
2:30 PM - 0 PPM (#4 OPENED)
2:34 PM - 5 PPM
2:35 PM - 25 PPM
2:37 PM - 55 PPM
2:39 PM - 50 PPM
2:40 PM - 25 PPM
2:45 PM - 5 PPM
2:50 PM - 0 PPM
3:45 PM - 0 PPM (#5 OPENED)
3:49 PM - 25 PPM
3:50 PM - 40 PPM
3:52 PM - 35 PPM
3:55 PM - 15 PPM
4:00 PM - 0 PPM
4:05 PM - 0 PPM (#4 OPENED)
4:06 PM - 40 PPM
4:07 PM - 53 PPM
4:08 PM - 30 PPM
4:10 PM - 25 PPM
4:15 PM - 15 PPM
4:20 PM - 5 PPM
4:25 PM - 0 PPM
8:25 PM - 0 PPM (#2 OPENED)
8:30 PM - 5 PPM
8:33 PM - 20 PPM
8:35 PM - 20 PPM
8:40 PM - 0 PPM

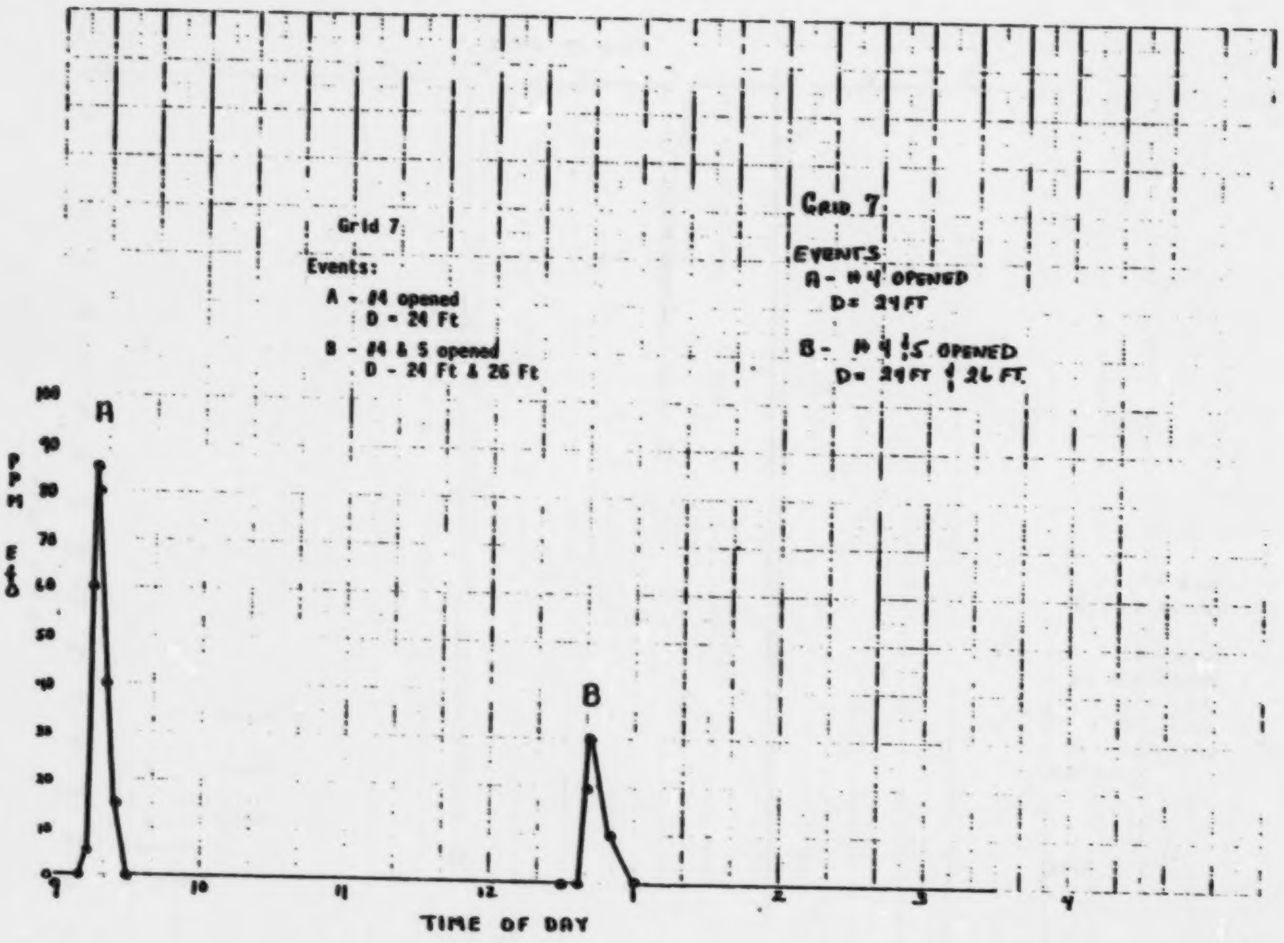

PROCESS SAMPLE
CENTER OF #4 & #5
28 IN. B2H
P
P
M
E
t
O
900
850
800
750
700
650
600
550
500
450
400
350
300
250
200
150
100
50
9
10
11
12
1
TIME OF DAY
461510

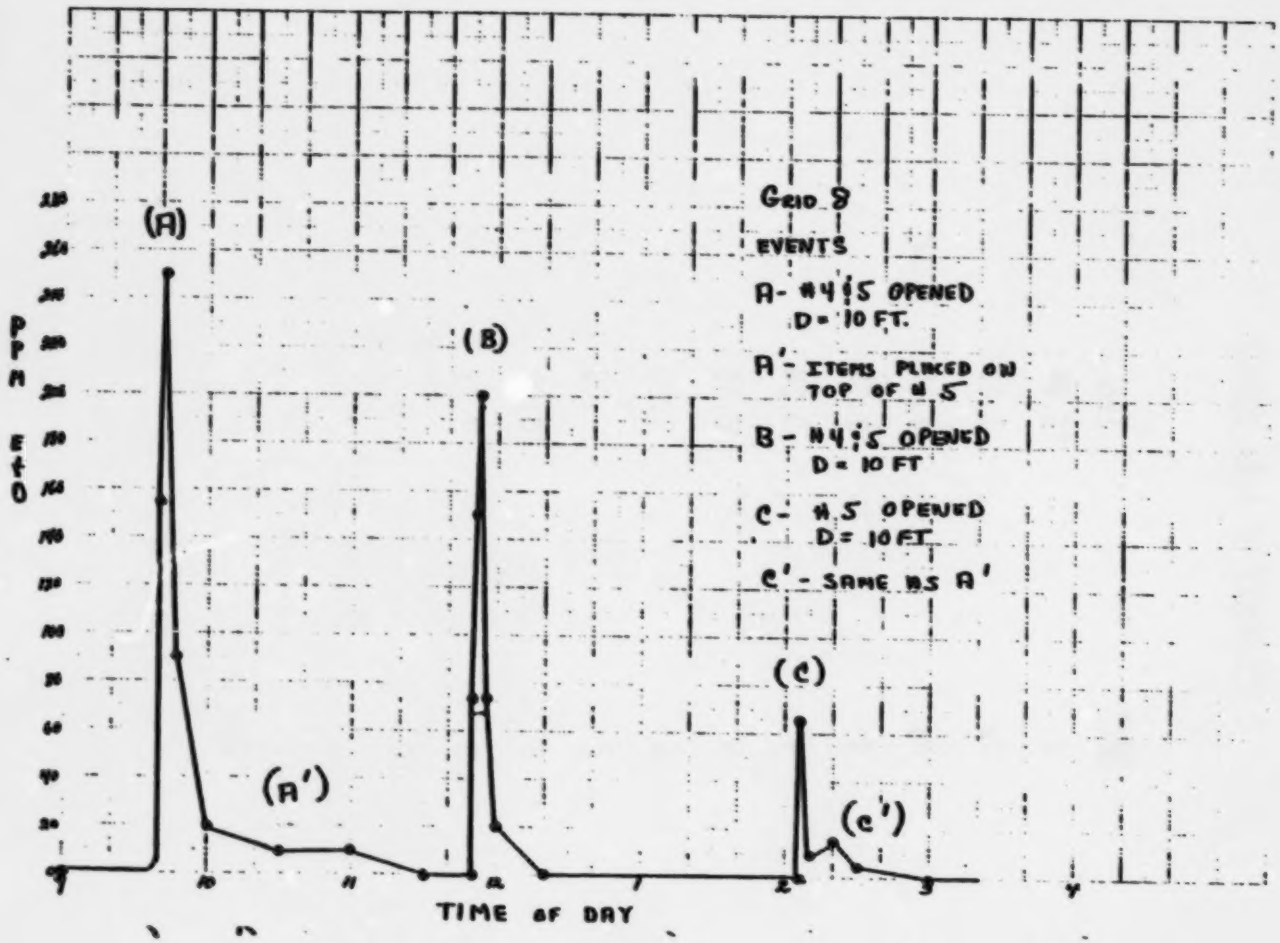

Grid 1
Events:
A - #5 opened
D = 27 Ft
B - #4 opened
D = 29 Ft
GRID 1
EVENTS:
A - #5 OPENED
D= 27 FT
B- #4 OPENED
D= 29 FT
A
B
PPM EtO
100
90
80
70
60
50
40
30
20
10
0
7
8
9
10
11
12
1
2
3
TIME OF DAY


Grid 2
Events:
A - #4 opened
D = 21 Ft
B - #2 opened
D = 10 Ft
Grid 2
Events:
A - #4 OPENED
D= 21 FT.
B - #2 OPENED
D=10FT
A
B
PPM EtO
260
240
220
200
180
160
140
120
100
80
60
40
20
4
5
6
7
8
9
10
11
12
TIME OF DAY


Grid 3
EVENTS:
A- #2 OPENED
D= 24 FT
B- #4 & 5 OPENED
D= 24 & 22 FT.
A
B
PPM
180
170
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
7
8
9
10
11
12
1
2
3
TIME OF DAY


Grid 6
Events:
A - #4 opened
D = 11 Ft
B - #5 opened
D = 9 Ft
C - #5 opened
D = 9 Ft
Grid 6
EVENTS:
A - #9 OPENED
D= 11 FT.
B - #5 OPENED
D= 9 FT.
C - #5 OPENED
D= 9 FT
A
B
C
P
P
M
H2O
180
170
160
150
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
7
8
9
10
11
12
1
2
3
4
TIME OF DAY


Grid 7
Events:
A - #4 opened
D - 24 Ft
B - #4 & 5 opened
D - 24 Ft & 26 Ft
GRID 7
EVENTS
A - #4 OPENED
D= 24 FT
B - #4 & 5 OPENED
D= 24 FT & 26 FT
A
B
PPM EtO
100
90
80
70
60
50
40
30
20
10
0
9
10
11
12
1
2
3
4
TIME OF DAY

Grid 8
EVENTS
A- #4 & 5 OPENED D= 10 FT.
A' - ITEMS PLACED ON TOP OF # 5
B - #4 & 5 OPENED D = 10 FT
C - #.5 OPENED D = 10 FT
C' - SAME AS A'
(A)
(A')
(B)
(C)
(C')
PPM EtO
280
260
240
220
200
180
160
140
120
100
80
60
40
20
0
9
10
11
12
1
2
3
4
TIME OF DAY

SUMMARY OF AREA SURVEY

GRID	TWA	
1	1.96	
2A	1.47	
2B	1.16	3.38*
3	2.94	
4	0.24	
5	0.43	
6	3.20	
7	2.09	
8	10.04	
9	2.73	
10	0	

*2ND SHIFT

APPENDIX C

PRACTICES RELATIVE TO WORKER EXPOSURE AT SELECTED SITES

TABLE C-1

PRACTICES RELATIVE TO WORKER EXPOSURE AT
HEALTH CARE FACILITIES

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[f]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Arizona Site A	3M([illegible])/ 2/10	100% ETO	Vented to atmosphere.	10	Workers wear no protective clothing or equipment.	Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (11,876 ft^3). Mechanical area ventilation with 17.6 air changes per hour. Airflow is from ETO work area toward non-ETO work area.	Limited access to sterilization area. Utilize 4 aerators. Treated materials are transferred from sterilizer to aerator in basket or on cart; treated materials are not transported by hand. Have preventative maintenance agreement with 3M for its chambers; Castle unit serviced in-house (includes filter change and gasket check). Employees received lectures and slide program on sterilization process.	Monitoring has been done in the past and is being conducted at present. Equipment used for monitoring includes: Wilks-Miran 1A; Century Organic Vapor Analyzer; Gas Tech Solid State; and JXC charcoal and gas chromatograph.
	3M(4000)/ 4/1	100% ETO	Vented to atmosphere.						
	Castle 7280/ 70/11	12% ETO 88% Freon®	Liquid/gas separator to atmosphere.		Castle chamber is unloaded immediately at end of cycle.				

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Arizona Site 8	Castle (3043)/ 3/3	12% ETO 88% Freon®	Vented to water drain.	10[d]	Not available.	None specified.	Sterilization conducted in Central Supply in general packaging and processing area (Central Supply measures 44' x 24' x 9.25'; ETO work area measures 10' x 9' x 9.25'). Environment is controlled through air conditioning with 10 air changes per hour. Direction of airflow is from non-ETO areas to ETO work area. Aerator located in separate 7400 ft^3 room (sterile stores).	Access to ETO work area is limited to ETO sterilization workers. Other work practices not detailed.	Not available.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[c]	
Arizona Site C	AMSCO/ 30/5	12% ETO 88% Freon®	Exhausted to sewer.	2	Not available.	Chamber equipped with door interlock to prevent opening of door before completion of cycle. 3M units equipped with purge system and interlocking door mechanism.	Sterilization conducted in Sterile Processing and Distribution area (SPD) (12,977 ft^2). Supplied air positive with 10.9 air changes per hour. Direction of airflow is from ETO work area to non-ETO work area.	Access to both ETO work areas is limited to ETO sterilization workers. At end of cycle, operator opens doors and then, after 15 minutes, unloads sterilizer. Operators wear gloves when retrieving treated material from sterilizer. Operators receive ongoing training, lectures, slides, and written exams. Quarterly inspection of sterilizer performed by hospital engineering service.	District Engineer Safety Inspector used Wilks-Miran to monitor ETO work area; additional data were not reported.
	3M (403)/ 4/5	100% ETO	Vented to outside atmosphere.						
	3M (400)/ 4/4	100% ETO	Vented to outside atmosphere.						
	3M (200)/ 2/3	100% ETO	Vented to outside atmosphere.	2			Sterilization conducted in Decontamination area (11,112 ft^3). Supplied air negative with 2 air changes per hour. Direction of airflow is from ETO work area to non-ETO work area.		
	3M(200)/ 2/3	100% ETO	Vented to outside atmosphere.	3					

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Arizona Site B	3M (200)/ 2/1	100% ETO	Vented to sewer.	1	Not available.	Not available.	Sterilization conducted in respiratory therapy area (5' x 12' x 8'). Mechanical area ventilation.	Access to both ETO sterilization areas is limited to ETO sterilization workers. Sign is posted next to sterilizer indicating that after door is opened operator must wait 5 minutes before removing basket. New employees receive complete orientation on ETO procedures. Hospital maintains preventive maintenance agreements with sterilizer manufacturers for inspection and service.	State Compensation of Arizona conducted monitoring in 1978 and 1979 using Wilks-Miran; no problems reported. Another hospital conducted monitoring at this hospital in 1979 using Wilks-Miran; found TWA levels to be below 50 ppm. Hospital purchased its own Wilks-Miran in 1980; tests have not been made as of August 1980.
	3M (400)/ 4/5	100% ETO	Vented to atmosphere.	4	Treated materials carried in basket by operator to aeration chamber located in a room 12' away from ETO work area.	Not available.	Sterilization conducted in Supply Processing and Distribution (SPD). (36' x 36' x 8'). Mechanical area ventilation with 20 air exchanges per hour (267 cfm).[f] Positive airflow in ETO work area from non-ETO work area.		
	Castle (4060)/ 60/6	12% ETO 88% Freon®	Vented to atmosphere.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators^{a}	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{f}
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
California Site A	AMSCO/ 30/3	12% ETO 88% Freon®	Vented to outside atmosphere.	11-14^{d}	Not available.	Multiple post-vacuums.	Sterilization conducted in Central Supply (18' x 14½' x 14½') with 20 air changes per hour.	Each sterilizer is opened for 15 minutes before retrieval of sterilized materials. Gloves are worn by workers when material transferred to aerators (2) or open shelf unit (1) for aeration. Open shelf aeration is conducted at least 20 ft. from any working areas and has no employee traffic. List of hazards associated with ETO are posted near chambers. Workers receive initial and continuous in service training. Preventative maintenance contract for chambers with manufacturers. Access to sterilization area is limited to (but not partitioned from) sterilization technicians.	None
	3M(202)/ 4/3	100% ETO	Vented to outside atmosphere.			One post-vacuum. Unit has interlock door and air purge.			

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[b,c]	
California Site B	3M(400B)/ 4/<1	100% ETO	Vented to atmosphere.	7	Aerator is vented to room atmosphere at present. In the future, it will be vented to outside atmosphere.	Not available.	Sterilization conducted in a separate room that is part of Central Supply (8' x 6' x 10'). Passive area ventilation with 8 air changes per hour. Direction of airflow is to ETO work area from non-ETO work area.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, operator opens chamber door and leaves area for 15 minutes. Operator transfers treated materials to aerator or open table in metal wire basket. Packages placed on table are marked "Do not air. Do not use until (1 week)." They are then sent to appropriate department for ambient aeration. Workers receive training from 3M and attend ETO seminars. Hospital has preventive maintenance contract with 3M. Follow-up work performed by hospital engineering department.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft³)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
California Site C	(2) 3M/ Not available/ Not available	Not available.	Not available.	5	Not available.	Aerator vented to outside atmosphere	Sterilization conducted in Central Service (18' x 24' x 8'). Mechanical area ventilation with 6 air changes per hour. Direction of air-flow is towards non-ETO work areas from ETO work area.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, an operator opens chamber door and waits 10 minutes before unloading chamber. Treated items transported in baskets, not by hand. Workers receive on-the-job training in sterilization procedures. Preventive maintenance performed by hospital Bio-Med Services.	Workplace monitored by OSHA; no additional data reported.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Colorado	3M (400)/ 4/3	100% ETO	Continuous purge via pipe to outside atmosphere.	10	Not available.	3M sterilizers have interlocks to prevent opening of door prior to cycle completion. In 3M (4000) unit, the cycle can be aborted, in which case the gas is purged before door can be opened. If gas is not purged, only service men can unlock unit. Utilize 3 aerators; 2 vent to room atmosphere, 1 vents to outside atmosphere.	All sterilizers and aerators located in Central Supply (35' x 30' x 8'). Mechanical area ventilation with 8 to 10 air changes per hour.	Access to ETO work area is limited to ETO sterilization workers. At completion of cycle, door is unlocked and opened approximately 2 inches for 15 minutes. Then door is opened completely for another 15 minutes before contents are removed. Workers wear rubber gloves. Move sterilized materials directly into aerators. Workers receive initial orientation and proficiency testing for sterilization operation, as well as a refresher course every 6 months. Quarterly inspection and maintenance by manufacturers with additional calls as deemed necessary at other times. Additional supervisor hired to monitor all aspects of sterilization, aeration, and storage of sterile supplies.	None
	3M (4000)/ 4/1	100% ETO							
	Castle (3043)/ 9/2	12% ETO 88% Freon®							

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators^{a}	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{c}
	Equipment Manufacturer/ Size (ft^{3})/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{b}	Work Practices^{c}	
Connecticut Site A	AMSCO (Model-11'on M65G)/ 5.5/9	12% ETO 88% Freon®	Vented to outside atmosphere.	14^{d}	Access to ETO work area is not limited to sterilization workers.	Aerator vented to outside atmosphere.^{e}	Sterilization conducted in Central Supply (30' x 34' x 9'). Mechanical area ventilation and window aeration with 5 to 10 air changes per hour. Direction of airflow is to non-ETO work area from ETO work area.	Chamber door is opened at end of cycle and left open for 15 minutes before unloading. Operators wear gloves when transferring treated material to aerator. Employees receive sterilizer training when first introduced to sterilization operations. Sterilizer serviced quarterly by AMSCO.	In-house analysis conducted of air samples taken before and after completion of sterilizing cycle; hospital reports that samples were within "normal" limits.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Connecticut Site 8	3M (400B)/ 4/4	100% ETO	Continuous purge to outside atmosphere.	14[d]	Not available.	3M sterilizers equipped with interlocks to prevent door from opening while cycle is operating. Two aerators vented to outside atmosphere.	Sterilization conducted in Central Supply (combination of work room and sterilization room). Sterilizers and aerators are located in wall between sterilizer room (30' x 6'7" x 10') and work room (30' x 17' x 10'). Sterilizer room is mechanically vented to outside atmosphere with 12 air changes per hour. Direction of airflow is from non-ETO area (work room) towards ETO work area (sterilizer room) to outside atmosphere.	Access to ETO work area limited to employees in general work areas; however, no one is allowed in sterilizer room during sterilization operations. At end of 3M units' cycle, door is opened and operator waits 10 minutes before removing treated materials. At end of AMSCO unit's cycle, door is opened and room is evacuated for 10 minutes before removing treated materials. Operators wear cotton gloves when unloading chamber. Each worker receives 12 hours per year of ETO training, including ETO seminars, tapes, slides, video cassettes, movies, and lectures. Preventive maintenance performed on chambers every 6 months. Maintenance includes replacement of gasket, spray nozzle, filter, and other small parts susceptible to wear. Timing and sequence of operation are checked out, as is sterilizer, for broken mechanical parts.	AETNA Insurance Co. has analyzed air around sterilizer and has not detected any concentrations of ETO; additional data was not reported.
	3M (400B)/ 4/1	100% ETO	Continuous purge to outside atmosphere.						
	AMSCO/ 1.63/14	12% ETO 88% Freon®	Mechanical purge to sterilization room.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Delaware	3M (4XL)/ 4/6	100% ETO	Vented to outside atmosphere.	4	Not available.	Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply Service (23' x 18' x 12'). Ventilated by air conditioner with circular airflow.	Access to ETO work area is limited to ETO sterilization workers. At end of cycle, operator opens door slightly and leaves area for approximately 15 minutes. Treated materials are transferred in [illegible] in metal baskets. Use 3M ETO booklet to train workers on sterilization procedures. Hospital has maintenance contract with 3M for inspection and service of chamber.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators^a	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^c
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^b	Work Practices^c	
Florida Site A	AMSCO (SD-6882)/ 30/3	12% ETO 88% Freon®	Vented to outside atmosphere	3	ETO chambers not regularly inspected.	Chamber has safety lock, which is engaged by chamber pressure. Chamber has door interlocks, which prevents cycle from beginning unless door is properly latched.	AMSCO (SD-6882) and Advanced Instruments, Inc. chambers are used in Central Supply (27' x 27' x 10'). Other AMSCO unit used in surgery work room (26' x 24' x 8'). Each room has mechanical ventilation with 10 air changes per hour. Each room is equipped with one aerator and the Central Supply area has 4 open shelf aeration units.	Access to each ETO work area is limited to ETO sterilization workers. Chamber door opened 6 inches for approximately 15 minutes. Treated materials are then loaded into aerator by operator wearing cotton gloves. Workers wear scrub gowns (primarily for infection control). Continuous on the job training in ETO sterilization procedures; operator in Central Service area must be a registered CSA Technician in order to operate ETO sterilization equipment (as of September 1980). AMSCO services chambers when required.	None
	Advanced Instruments, Inc. (Advanced Mark III)/ 2/6	100% ETO	Not in use at present.	3					
	AMSCO/ 8/2	12% ETO 88% Freon®	Fan with duct work.	4					

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Florida Site B	AMSCO (MC3G)/ 3/7	12% ETO 88% Freon®	Condenser water to floor drain.	5	Not available.	Aerator vented to roof exhaust fan.	Sterilization conducted in Central Supply (19'6" x 20'4" x 8'). Mechanical area ventilation with air movement of 1100 cfm[d] (supplied) and 1000 cfm[d] (exhausted). Direction of airflow is to ETO work area from non-ETO areas. Additional exhaust fan near floor drain (290 cfm 6"); removes escaping vapor from condenser water drain.	Access to ETO sterilization area limited to ETO sterilization workers. At end of cycle, chamber door is opened approximately 6 inches for 15 minutes before removal of cart. Operator wears gloves when pulling treated materials from sterilizer and placing them on rack to aerate for 2 hours. New workers given procedure book and instruction by senior employee. A quarterly maintenance schedule is maintained for electrical motor and pump, recorder door, and manual test.	Air samples at hospital monitored by Boehringer Laboratories, Inc. Hospital reports that results were positive; no additional data were reported.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Georgia Site A	AMSCO (Cryotherm)/ 3/9	12% ETO 88% Freon®	Vented to room located between gas and steam sterilizer.	16[d]	Access to ETO work area is not restricted.	Not available.	Sterilization conducted in Central Service (25' x 15' x 8'). Passive area ventilation with direction of air-flow from ETO work area to non-ETO work area.	Safety precautions are posted and enforced.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Georgia Site 9	AMSCO (Cryotherm)/ 9/4	12% ETO 88% Freon®	Vented to outside atmosphere.	15[d]	Not available.	Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (31' x 14' x 9'). ETO sterilization conducted in same room as steam sterilization; ETO chamber located at one end of room, away from other work areas. Mechanical area ventilation with 10 air changes per hour. Airflow is from ETO work area to outside atmosphere.	Limited access to Central Supply area. At end of sterilization cycle, chamber door is opened at least 6 inches, and employee moves from ETO work area for at least 15 minutes. Sterilized materials are placed in Castle aerator, which is next to ETO sterilizer. Employees wear disposable gloves when handling these items. Workers are trained on ETO procedures with written instructions and testing. These instructions are reviewed and/or updated at least annually. Preventative maintenance contract with manufacturer for inspection and service every other month.	Private company monitored workplace to determine if employees might be exposed to excessive concentrations of ETO. Using a Draeger multi-gas detector, the company found levels of zero ppm at chamber door during changing of sterilizer; at drain; chamber door with door open after cycle; and at aeration door after 12 hour aeration cycle. Levels of 35 ppm were detected within chamber after sterilization cycle.

TABLE C-1 (CONTINUED)

	Sterilization/Fumigation Equipment					Control Measures Implemented			
State/ Site	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System	Total Number of Operators[a]	Potential Exposure Situations	Equipment Design	Workplace Design[b]	Work Practices[c]	Monitoring of Workplace for Residual Levels of ETO[d]
Illinois Site A	AMSCO/ 6/10	12% ETO 88% Freon®	Vented to sewer and to outside atmosphere.	6	Not available.	At end of cycle, there are two filtered air purges. Sterilizer equipped with safety lock door.	Sterilization conducted in Central Service (44' x 22' x 10'). Negative pressure room at rear of all sterilizers and aerators, with large 23 inches extractor fan continuously in operation. Positive pressure ventilation in clean area (front of sterilizers and aerators) with 7-10 air changes per hour. Direction of air-flow is towards ETO work area from non-ETO work area.	Access to sterilization work area limited to authorized Central Service personnel. At end of sterilization cycle, chamber door is opened 6 inches and the immediate area is cleared for at least 15 minutes; operator lets colleagues know of door being opened. Operators wear heavy cloth gloves when transferring sterilized materials to aerator treated items are subjected to 8 changes of air per minute for a minimum of 16 hours for a 3 hour isolation load and for a minimum of 12 hours for a normal 3-hour sterilization load. New technicians receive thorough orientation/training and are subject to close supervision by Senior Technician and Department Supervisor at all times. Every 3 months a Department Inservice Education Revision is done with all technicians. Hospital has quarterly PMA contract with AMSCO. Supervisor of Central Service keeps close supervision of technicians to check for poor work habits and "complacency."	In the past two years, Central Service has had two complete monitoring surveys done for residual ETO concentrations: one done by Central Supply and the other done by Risk Management Insurance Company (Liberty Mutual). Gas chromatography was used for both monitorings. No specific problems were identified and all levels were considered safe for TWA concentrations. Supervisor also uses Leak TEC Tracer unit to test for 'silent' leaks at all pipe fitting unions each Friday. This action is documented in Preventive Maintenance record kept in Department.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Illinois Site B	AMSCO (Cryotherm)/ 30/9	12% ETO 88% Freon®	Vented to outside atmosphere.	1	Not available.	Sterilizer equipped with pulsing vacuum. Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (830 sq. ft.). Sterilization area is not in a separate room but is separated from other work areas. Exhaust fans in windows at rear of sterilizer and fans in front of sterilizer. Direction of airflow is toward ETO work area from non-ETO work area.	Access to ETO work area limited to sterilization workers. At end of sterilization cycle, chamber door is cracked, left open for 15 minutes before the treated material is transferred to aerator. Workers follow AHA ETO use guidelines, view AMSCO slide presentation on ETO sterilization, are given articles to read on ETO. Hospital has PMA Agreement with AMSCO for quarterly service and inspection. Exhaust fans are turned on when ETO sterilization cycle begins and remains on until end of aeration cycle.	Although hospital does not conduct monitoring at present, Biomedical Engineering Department is acquiring a gas analyzer to check and monitor levels of ETO on a frequent basis.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Illinois Site C	AMSCO (Cryotherm)/ 20/3.5	12% ETO 88% Freon® (Freon-12)	Vented through filter to ventilation system.	4	Not available.	Interlock on chamber door to prevent opening of door before end of cycle. Prior to opening of chamber door, the sterilizer performs a 10-minute purge cycle to expel residual ETO gas. Hospital is considering installation of hood above gas sterilizer connected to ventilating system that would draw any additional vapors up and out of department when chamber door is finally opened.	Sterilization conducted in Central Supply (24' x 36' x 9'). Mechanical area ventilation with 10-33 air changes per day. Direction of air flow is to ETO areas from non-ETO work areas. An air return vent is located above the aerator exhaust (all of which is in an area enclosed by brick walls).	Access to ETO work area limited to ETO sterilization workers. At end of sterilization cycle chamber door is opened 1-2 inches and attending technician leaves sterilizer area for 30 minutes before retrieval of treated items. Technicians wear only standard scrub gear when operating chamber. Technicians are instructed by department coordinator during job orientation on proper procedure for working with gas sterilization. All Central Supply equipment is on regular preventative maintenance schedule maintained by hospital engineering and maintenance department.	American Hospital Supply Company tested with hand-controlled gas chromatograph on hospital's sterilizer and reported not finding any leaks.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Illinois Site B	AMSCO (8656 PD)/ 30/5	12% ETO 88% Freon®	Vented through ceiling into duct work.	23[d]	Not available.	Aerator vented to duct work through pipe in ceiling.	Sterilization conducted in Central Supply (32' x 24' x 8') ETO work area (separate room) is 2 ft. long x 21 ft. wide. Mechanical area ventilation with 26 air changes per hour. Direction of air-flow is away from ETO work area.	Access to ETO work area is limited to sterilization workers. At end of cycle, the operator opens chamber door, then leaves area for a short period. Operator occasionally wears gloves. New operators receive on the job training in sterilization techniques; periodic in-service review for all employees. Maintenance conducted primarily in-house. Maintenance man is taking an AMSCO maintenance training course. Use 60 inch aerator that accepts sterilizer cart; therefore, treated materials do not have to be handled by operator.	At one time, Wilks-Miran 103 Ambient Air Analyzer was used to monitor ETO work area. Hospital reports that no problems were detected; additional data not available.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Illinois Site E	Castle (3043)/ 8/2	12% ETO 88% Freon®	Vented to atmosphere above sterilizer and purges through drainage system.	9[d]	Access to sterilization area is limited to 1 to 2 employees, but 9 other employees work in general area.	Utilize Castle Model 4041 aerator and two sections of open shelves for aeration.	Sterilization conducted in an isolated area within Central Service. ETO work area measures 20' x 24' and Central Service measures 44' x 38'. Mechanical area ventilation with 15 air changes per hour. Direction of air-flow is towards ETO sterilizer from ETO work area.	Not available.	Not available.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Kansas Site A	Castle/ 30/15	12% ETO 88% Freon®	Vented to outside atmosphere.	1	Access to Central Supply ETO work area is not limited to ETO operators.	One post-vacuum. Power door interlock. Aerator vented to outside atmosphere.	Castle sterilizer: Sterilization conducted in Central Supply (40' x 40'); ventilation is passive with 8 air changes in room per hour; direction of airflow is to ETO work area.	At end of cycle, operator opens chamber door and leaves work area for 15 minutes. Sterilized materials are transported from sterilizer to aerator in wire baskets. Operators receive inservice education on ETO sterilizer from department management. Hospital Engineering Department inspects and services equipment daily.	Monitor workplace on a weekly basis using National Draeger-Vacuum Tube Collection and Surgical-Analog Electrical Metering Device. No problem areas noted.
	AMSCO/ 9/2	12% ETO 88% Freon®	Vented to outside atmosphere.	1	Not available.	Power door interlock. Aerator vented to outside atmosphere.	AMSCO sterilizer: Sterilization conducted in ambulatory surgery; (20' x 30'); ventilation is passive with 12 air changes in room per hour; direction of airflow is to ETO work area from non-ETO work area; access to this area limited to sterilization workers.		

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[d]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Kansas Site B	3M (400)/ 4/>1	100% ETO	Vented to outside atmosphere.	1	Not available.	Aerator vented to utility room, which is vented to outside of building via exhaust fans.	Sterilization conducted in Processing Room of Central Supply (10' x 35' x 8'). Mechanical area ventilation. Rate of air movement is: 900 cfm[e] (return air vents over front of sterilizer) and 400 cfm[e] (exhaust in mechanical aerator). At one time, both sterilizer and aerator were used and vented into the same room with the operator; the mechanical area has since been partitioned off.	At end of sterilization cycle, chamber door is opened about 6 inches and the area is vacated for 15 minutes. Workers wear gloves when removing basket (containing sterilized materials) from sterilizer and placing in aerator. Operators receive written policy and procedures on ETO usage and in-depth training on the job. Routine visual inspection of chamber conducted, including leakage checks and internal cleaning.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Louisiana	AMSCO (MB5G) 8/5	12% ETO 88% Freon®	Exhausted to sewer.	5-6	Not available.	Two post-vacuums. Door lock actuated under pressure. Three aerators used; vented to atmosphere.	Sterilizer and aerators located in Central Service area (144) sq. ft.). Mechanical area ventilation in work area with 10 air changes per hour. Airflow is from non-ETO areas to ETO work area.	Access to ETO work area limited to ETO operators. Operators follow AMSCO guidelines for use of ETO sterilizers and aerators. These guidelines, as well as ASHCSP guidelines, are posted on wall next to sterilizer door. Materials are sterilized on a loading car. Loading car is pulled to aerator and pushed inside. Workers wear cotton gloves when removing biological indicator from test pack. Worker training includes: ongoing program taught by director of central service and films on ETO (purchased from AMSCO and Castle). Monthly program of equipment inspection and maintenance.	Had outside source monitor process one time. Found high levels of ETO when sterilizer first opened, but levels down to less than 10 ppm within 7 minutes.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[e]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Maryland Site A	3M (400)/ 4/6	100% ETO	Vented to outside atmosphere	13[d]	Processing staff works in area adjoining ETO work area.	Chamber equipped with interlocks to prevent opening of door until completion of cycle. Multiple post-vacuums. Chamber equipped with automatic door. Aerator vented to outside atmosphere.	Sterilization conducted in Supply, Processing, and Distribution (SPD) (14,000 ft^3). Mechanical area ventilation with 11 air changes per hour. Direction of airflow is from ETO work area to non-ETO work area. Following mechanical aeration material is placed on designated shelves.	Access to ETO work area limited to Processing staff. At end of cycle, both chamber doors are opened 6 inches for 15 minutes (AMSCO door automatically controlled to open 6 inches); no personnel allowed near sterilizer door when first opened. Operators wear cotton gloves when removing cart from sterilizer and placing it in aerator. New employees instructed in procedures for packaging and operating sterilizers by Lead Technician; employees take return demonstrations until employee is knowledgeable of complete procedure; In-service classes are scheduled during year by supervisor. Classes may be taught by representatives of AMSCO and 3M Company. Maintenance personnel assigned daily to sterilizer area. Complete preventive maintenance program for each piece of AMSCO equipment by hospital Maintenance Department personnel. Maintenance check list is signed by supervisor. Hospital has maintenance contract with 3M Company for quarterly inspection and maintenance.	Draeger Multi-Gas Detector supplied by the United States Fidelity and Guaranty Insurance Company was used in February 1980. Levels of 25 ppm were detected.
	AMSCO (Combination Gas/Steam)/ 30/2	12% ETO 88% Freon®	Exhausted to sewer.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Maryland Site B	AMSCO (Cryotherm)/ 13/3	12% ETO 88% Freon®	Exhausted to drain.	Entire operating room staff.[d]	Access to both sterilization areas is not restricted.	Not available.	Sterilization conducted in operating room (15' x 20' x 9'). Mechanical area ventilation with 20 air changes per hour. Direction of airflow is from non-ETO work area to ETO work area.	At end of cycle, door is opened approximately 6 inches and all operators leave area. Treated materials are placed in basket or carriage and are lifted or pulled to appropriate aerator. Operators wear gloves during this process. ETO sterilization procedures reviewed annually. Hospital has bimonthly inspection of AMSCO equipment and quarterly inspection of 3M equipment by manufacturers.	United States Fidelity and Guaranty Company monitored for levels of ETO. Levels of 500 ppm after 8 minutes were detected at open door of 3M unit. Other levels detected range from 0 to 90 ppm. 90 ppm detected in 9 minutes approximately 3 inches above the floor drain during air cycle of AMSCO unit. 50 ppm were detected in 9 minutes after opening AMSCO chamber. Draeger pump with ETO Detector Tubes (30 pump strokes per each test) was used in monitoring. In response to high levels of ETO, hospital uses 3M unit only when "cold" cycle needed; evacuates entire sterilization area at end of cycle, rather than waiting only 15 minutes; and installed local exhaust at drain and at chamber door of AMSCO unit.
	AMSCO (Cryotherm)/ 24/5	12% ETO 88% Freon®	Local exhaust for drain and for door.	12[d]		Two 3M aerators vented to room atmosphere. One AMSCO aerator vented to general exhaust (hospital' air handling system does not recirculate air).	Sterilization conducted in sterile processing area; general work area measures 81' x 60' x 10'; ETO work area measures 26' x 20' x 10'. Mechanical area ventilation with 20 air changes per hour. Direction of airflow is from non-ETO area to ETO work area.		
	3M (202)/ 2/not available	100% ETO	Copper vent to roof.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Maryland Site C	3M/ 4/5	100% ETO	Vented to outside exhaust system through copper tubing.	Not available.	Not available.	Not available.	Sterilization conducted in Central Supply. Standard air conditioning for ventilation with 1-3 air changes per hour.	Access to ETO sterilization area limited to ETO sterilization workers. Operators follow ASHCSP guidelines for opening chamber door at end of sterilization cycle (15 minutes aeration with door open 6 inches). Employees wear cloth gloves while transferring treated materials in wire baskets to aerator. In-service training program on ETO procedures held by director of Central Supply; manufacturer representative holds program every quarter. Hospital conducts preventive maintenance on equipment every quarter.	None
	3M/ 4/3	100% ETO	Vented to outside exhaust system through copper tubing.			Three aerators vented to outside atmosphere.			

TABLE C-1 (CONTINUED)

	Sterilization/Fumigation Equipment					Control Measures Implemented			
State/ Site	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System	Total Number of Operators^a	Potential Exposure Situations	Equipment Design	Workplace Design^b	Work Practices^c	Monitoring of Workplace for Residual Levels of ETO^c
Maryland Site B	AMSCO/ 4/12	12% ETO 88% Freon®	Vented to sewer drain.	8	Aerator vented to room.	Multiple post-vacuum.	Sterilization conducted in Central Service. Mechanical area ventilation, with non-recirculating air (10-12 air changes per hour.) Direction of air flow is from ETO area to non-ETO area.	Access to both sterilization areas limited to sterilization workers. At end of cycle, door is cracked open and left in that position for at least 10 minutes before chamber is unloaded. Sterilizer operator wears cotton gloves when pulling sterilizer rack from sterilizer to aerator. Rubber gloves worn during cleaning of chamber, rack and carriage; complete jumpsuit, shoe covers, gloves, mask available and recommended for personnel performing maintenance tasks; a Scott Air-pact is available for emergency situations. Workers receive initial orientation-training which includes lecture, clinical supervision and written testing. Employee is not allowed to perform ETO sterilization alone until able to pass written examination with a ranking of 85 percent or better and when supervisor verifies proper performance. Yearly review of ETO with update and written testing, which is kept as part of employee record.	Environmental monitoring has been conducted twice. Measured ETO concentration of 10 ppm at aerator exhaust.
	3M (400)/ 4/2	100% ETO	Vented to outside atmosphere.	1	Aerator vented to room.		Sterilization conducted in Respiratory Therapy. Mechanical area ventilation, with nonrecirculating air (8-10 air changes per hour).		

TABLE C-1 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Maryland Site D (Concluded)								Manufacturers service chambers under preventive maintenance agreement and in-house maintenance personnel available to make immediate repairs.	

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators^a	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^c
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^b	Work Practices^c	
Maryland Site E	AMSCO/ 4.3/5	12% ETO 88% Freon®	Dedicated ducting to outside atmosphere.	22^d	Not available.	Two post-vacuums. Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (43' x 25' x 10'). Mechanical area ventilation with 6-8 air changes per hour. Direction of air-flow is toward non-ETO area from ETO work area.	Access to ETO work area limited to Central Supply workers (pregnant employees not allowed around ETO sterilization operations). AHA guidelines for ETO use in hospitals are posted next to sterilizer and followed by employees. At end of cycle, operator cracks door open 6 inches and leaves ETO work area for 10 minutes before unloading chamber. Operators wear vinyl gloves when transferring treated materials in wire basket from sterilizer to aerator. Gloves are disposed of after use. New employees receive 6-8 weeks orientation program run by hospital during which procedures are reviewed on a step-by-step basis; they also attend 1 week Educational Seminar run by AMSCO; experienced employees receive periodic refresher course. Hospital has PMA contract with AMSCO for monthly inspection and service.	Monitoring conducted in 1978 by Vital Signs, Inc. (Columbia, MD.), using Multi-Gas Infrared Spectrophotometer. Vital Signs detected the following levels of ETO at shoulder level: loading sterilizer 3 ppm unloading sterilizer 6 ppm during vacuum cycle 1-7 ppm 5 minutes after gas introduced...6 ppm 10 minutes after gas introduced...3 ppm 15 minutes after gas introduced...3 ppm 25 minutes after gas introduced...1 ppm. Vital Signs also detected at: above sterilizer door 20 ppm door seals 6-2 ppm aerator door lining 19 ppm ETO tank manifold 0 ppm.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators^a	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^c
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^b	Work Practices^c	
Massachusetts	AMSCO 8/14	12% ETO 88% Freon®	Vented to room atmosphere.	6^d	Access to Central Supply sterilization area not limited to ETO sterilization workers.	Chamber equipped with continuous purge system and with safety pressure door lock. Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply. Mechanical area ventilation with 10 air changes per hour. Direction of air-flow is towards ETO work area from non-ETO work area.	Central Supply Practices: At end of cycle, operator opens door, stands back away from door, and waits 15 minutes before unloading chamber. Operators wear gloves; operators receive initial indoctrination and subsequent refresher sessions. Hospital contracts with AMSCO for preventive maintenance; hospital conducts daily cleaning and observation of charts, dials, and gauges.	Massachusetts JHA Service performed monitoring with gas chromatograph and detected levels of 15.1 ppm in front of sterilizer after sterilization cycle with door opened and 21.6 ppm on cart traveling to aerator.
	3M (200) 2/6	100% ETO	Vented to outside atmosphere.	12^d	Access to Respiratory Therapy sterilization area not limited to ETO sterilization workers.	Aerator vented to room atmosphere (which is drawn by window exhaust fan to outside atmosphere).	Sterilization conducted in Respiratory Therapy Department. Sterilization room also used for equipment assembly and packaging (12' x 11' x 8'). Ventilation through window exhaust fan. Direction of air-flow is toward ETO work area from non-ETO work area.	Respiratory Therapy Practices: At end of cycle, chamber door opened, basket containing sterilized materials pulled out partially, and operator leaves room for 10-15 minutes. Operators receive initial indoctrination and individual refresher sessions if necessary. Interior and exterior of cabinet cleaned weekly; vacuum pump valves disassembled and cleaned quarterly.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[d]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Michigan Site A	Castle (3240)/ 30/3	12% ETO 88% Freon®	Vented to sewer.	3	Not available.	Multiple post-vacuums. Chamber equipped with interlocks to prevent opening of door prior to completion of cycle and with automatic doors. Separate exhaust fan, located above sterilizer, vents ETO gas to outside atmosphere. Aerator vented to outside atmosphere.	Sterilization conducted in Sterile Processing and Distribution, (10,733.1 ft^3). Mechanical area ventilation with 10.2 air changes per hour. Direction of airflow is from non-ETO work area to ETO work area.	Access to ETO work area limited to sterilization workers. At end of cycle, employee presses open door button and walks away from sterilizer; 15 minutes later, treated materials are transferred from sterilizer to aerator. Workers are given written instructions and then demonstration on how to operate sterilizer. Castle inspects and services sterilizer on a quarterly basis.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Michigan Site B	AMSCO (Portagas)/ 10" dia x 36" long/6	12% ETO 88% Freon®	Vented to outside atmosphere.	2	Not available.	Two aerators vented to outside atmosphere.	Sterilization conducted in Sterile Processing (an L shaped room in Central Supply) which measures 75' x 24' x 9' & 28' x 36' x 9'. Mechanical area ventilation with 6 air changes per hour. Direction of airflow is from non-ETO work area to ETO work area.	Access to both ETO work areas is limited to ETO sterilization workers. At end of cycle, operators open door and turn their backs to sterilizer door, then immediately place treated materials in aerator. Operators wear gloves when transferring treated items by hand into small aerator and when pulling loading cart to large aerator. Operators receive orientation every 6 months. Orientation program consists of discussion of ETO hazards, review of leak or exposure procedures, and handling of sterilized items. Quarterly and P.R.N. program of equipment inspection and maintenance.	Hospital uses gas detector to detect leaks every time an ETO tank is changed or if someone smells ETO.
	AMSCO (Medallion-M)/ 24/<1	12% ETO 88% Freon®	Vented to outside atmosphere.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators^a	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^c
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^b	Work Practices^c	
Minnesota Site A	Sybron/Castle (3240)/ 30/>1	12% ETO 88% Freon®	Continuous purge to sewer.	2	Not available.	Aerator is vented to outside atmosphere. Chamber equipped with interlock to prevent opening of door prior to completion of cycle.	Sterilization conducted in sterilization area of Central processing. Mechanical area ventilation with 6.7 air changes per hour. Direction of air-flow is to ETO work area from non-ETO work area.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, door is opened 6 inches and left in that position for 15 minutes before treated materials are removed. Protective gloves are worn. ETO sterilization procedures posted. In-service operator training. Items are stored in enclosed aerator. Will begin chamber manufacturer's preventive maintenance program in October 1980.	Marsh and McLennan Insurance Company monitored ETO sterilizer with Draeger in April 1980. No additional information was supplied.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Minnesota Site B	Castle (combination gas/steam)/ 60/4	12% ETO 88% Freon®	Vented to floor drain.	3	Not available.	Three aerators vented to outside atmosphere.	Sterilization conducted in Central Supply(40' x 30' x 8'). Area ventilation by ceiling diffusers with 6 air changes per hour. Direction of airflow is from non-ETO to ETO work area. Additional exhaust, check valves installed at gas manifold.	Access to work area is limited to ETO sterilization workers. At end of cycle, operator leaves the door open for 15 minutes before removal of treated materials. Operator wears gloves to remove carts or baskets from 3M sterilizer and to transfer them to aerator. The entire cart or basket is placed directly into aerator, located below sterilizer. Operators given initial orientation and periodic in-service seminars; follow AHA guidelines. Periodic maintenance performed by chamber manufacturers; hospital maintenance department changes filters, wipe gaskets, and cleans exterior and interior of chamber.	Insurance Carrier monitored with Variable Wave Length Spectrograph; no problems reported. 3M monitored with charcoal tubes; no problems reported. TWA levels from 5-8 ppm to 50-75 ppm at peaks were detected.
	Castle/ 60/4	12% ETO 88% Freon®	Vented to floor drain.						
	3M (400)/ 5/1	100% ETO Surgicot	Vented to outside atmosphere.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Minnesota Site C	3M (400)/ 4/4	100% ETO	Continuous purge to outside of building via copper tubing.	13	Treated materials left near the chamber when aerators are full. Aerators are vented to room atmosphere.	Interlocks are installed. Multiple post-vacuums by AMSCO chamber.	Sterilization conducted in Central Supply (15' x 45' x 8'). Mechanical area ventilation with 6 air changes per hour. Direction of air-flow is to ETO worker area.	Access to work area is limited to ETO sterilization workers. At the end of cycle, door is cracked for 15 minutes; door is immediately closed after removal of load. Materials are placed in aeration cabinets after sterilization cycle; if aerators are full, the materials are left near sterilization chamber until aerator(s) is available. New employees receive on-the-job and in-service training on ETO when available. Step-by-step procedures are provided in CSS Procedure Manual. Quarterly PMA contracted with manufacturer.	3M Medical Products Service Center and EO Monitoring Services conducted monitoring using Wilks-Miran Model 103 and/or TSI Model 1650 Air Velocity Meter; found inadequate air changes in the area improper ventilation for the area. Studying alternatives and consulting with mechanical engineers to propose remodeling budget for FY 80.
	AMSCO/ 8.8/6	12% ETO 88% Freon®	Drained to sewer.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Minnesota Site B	3M (202)/ 2/3	100% ETO	Vented to outside atmosphere by vacuum tube.	23	Not available.	Chambers equipped with interlocks to prevent opening of chamber door prior to completion of cycle.	Sterilization conducted in Central Service area (6'6" x 3'5" x 10'). Mechanical area ventilation with 12 air changes per hour. Work area equipped with 17 open shelf units.	Access to both work areas is limited to ETO sterilization workers. Operator waits 3 minutes between opening of door and retrieval of sterilized items. Operator wears rubber gloves when removing treated materials and placing them into aeration basket. Manufacturer representative trains employee regularly; no one operates machine before training. Biomedical engineer cleans water inlet weekly. Equipment inspection is covered by annual maintenance contract with the equipment manufacturer.	None
	3M (202/ 2/6	100% ETO	Vented to outside atmosphere.	20	Aerator is vented to room atmosphere.		Sterilization is conducted in the Inhalation Therapy (Technical Service) Department. Sterilization work area measures 16' x 11' x 10'. Rate of air exchange is 7 air changes per hour. Direction of airflow is through steam sterilizer venting system. Work area equipped with 10 open shelf units.		

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[d]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Minnesota Site E	Castle (3045)/ 8/not available	12% ETO 88% Freon®	Exhausted to sewer.	3	Operator stands behind door cracked at the end of cycle.	Multiple post-vacuums. Aerator vented to ceiling.	Sterilization conducted in Central Supply. Central Supply area measures 20' x' 20' 80'.	Access to sterilization area is limited to ETO sterilization workers. At end of cycle, door is cracked 2 inches for 15 minutes with operator standing behind the door. Operator wears gloves when transferring materials to aerator. In-service training is given to operators. Hospital maintains PMA contract with manufacturer; maintenance also performed by hospital and insurance company.	St. Paul Insurance Company tests ETO leakage levels every 6 months using Miran 103 Infrared Analyzer and DuPont low flow pumps and charcoal tubes. Highest value of 12.5 ppm was detected during exhaust phase in rear area of sterilizer. Appropriation will be made in FY 1981 for drawing venting pipe from aerator to outside and modifying gas unit for venting ETO in response to data obtained from monitoring.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Missouri	AMSCO/ 24/3	12% ETO 88% Freon®	Exhausted to floor drain.	5	Not available.	Aerator vented directly to outside atmosphere.	Central Supply area devoted strictly to the reprocessing of items for steri- sterilization. Mechanical area ventilation with 14-16 air changes per hour. Vents above sterilizer pull air directly into the equipment room or through the positive and negative flow to the decontamination area. Central Supply has its own air-conditioning and heating system which is vented directly to the outside atmosphere for patient protection. Two open shelf units and one mechanical aerator available for aeration.	Limited access to ETO work area. Workers follow AHACSP guidelines for chamber and aerator operations. Gloves are optional and caps are required when handling ETO items. All sterilizers are on maintenance program with manufacturer. Technicians provided with check-off sheet for ETO sterilization operations. Technicians that are pregnant cannot work in sterilization area. As a result of monitoring, several changes in ETO operations have occurred, including: 1. The following of AHACSP recommendations 2. Movement of ETO sterilization to a new area with a better venting system and new equipment 3. Start of routine maintenance and accurate keeping of those records 4. Event of routine in-service program on ETO sterilization annually 5. Start of in-service check-off sheets for accurate recording of what is learned and retained so vague points can be covered.	Monitoring is conducted every other month with the use of a Draeger Multi-gas detector. Testing is done during the cycle and immediately after the cycle at the floor drain, chamber drain, connection from the ETO tank to the sterilizer, and the area immediately outside the door at the time the door is opened. Only zero levels of ETO concentrations have been detected.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Montana	AMSCO (2025)/ 8.7/5	12% ETO 88% Freon®	Continuous purge via hose to sewer and vented to outside atmosphere.	4	Worker training on ETO sterilization procedures is not provided. There is no regularly scheduled program of equipment inspection and maintenance.	Aerator vented to outside atmosphere.	Sterilization conducted in room that is part of Central Supply. Dimensions of room are 12' x 8' x 8'. Passive area ventilation.	Access to ETO work area is limited to sterilization workers. Chamber door is cracked open for approximately 5 minutes before treated material is removed and placed in aerator. Operators wear cotton gloves when transferring treated material to aerator; treated material carried in wire basket.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
New Hampshire	AMSCO (Cryotherm)/ 8/10	12% ETO 88% Freon®	Vented to outside atmosphere	19[c]	Access to sterilization area is not limited to ETO sterilization operators.	Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply. Central Supply measures 2438 sq. ft. Mechanical area ventilation (ceiling ducts) with 10 air changes per hour. Direction of airflow is to ETO work area from general work area.	At end of cycle, chamber door is cracked open. Operators wear gloves. ETO sterilization procedures discussed in procedure manual provided to employees. In-house maintenance of sterilizers and ventilation system, with daily checks.	Central Supply evaluated for residual ETO levels by Technology in Medicine, Inc. (Newton Upper Falls, MA.) in Feb. 1980. Firm used Wilks-Miran 1A Analyzer to monitor and recommended that Central Supply improve ETO tank restraints and correct one tank system leak.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
New Jersey	3M Sterivac 202/ 2/6	100% ETO	Exhausted via copper pipe to outside atmosphere.	2	Not available.	Aerator vented to outside atmosphere.	Chamber located in Central Supply; Central Supply area is 50' x 30' 10'. ETO work space is 8' x 6' x 10'. Mechanical ventilation of general work area with 10 air changes in room per hour. Direction of air flow is from ETO work area towards non-ETO work area.	Limited access to ETO work area. Chamber door opened for 15 minutes before removing sterilized articles. Gloves available for workers. Workers receive ETO orientation and written test. Contract with 3M for semi-annual preventative maintenance plan.	Monitored in March 1979 by Biomedical Engineering Shared Technology (BEST). BEST reported that: A residual of ETO from the previous day's use was detected in the sterilizer. Gas inside sterilizer was monitored for about 30 minutes with door open, was recorded at 18 ppm maximum, and reduced to zero in 30 minutes. Level in room was zero and air circulation system quickly diluted ETO level in work area even with the sterilizer door open. During unloading of the sterilizer a maximum of 92 ppm was measured at top left of sterilizer. Procedure used in loading and unloading was good and the control of personnel and timing of loading and unloading cycle reduced personnel exposure to a minimum. Levels of 75 ppm for 15 minutes and 50 ppm for a work day were not reached.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
New York Site A	AMSCO (Medallion)/ 20/<2	12% ETO 88% Freon®	Vented to sewer.	6	Not available.	Multiple post-vacuum. Two air purges. Chamber equipped with safety lock to preventing opening of door until cycle is complete. Aerator vented to outside atmosphere.	Sterilization conducted in separate room (10' x 8' x 8') located off general work area of Central Supply. Passive area ventilation. Filtered air from open window moves to exhaust grill located in ceiling over sterilizer. Direction of air-flow is from non-ETO work area to ETO work area.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, operator opens door approximately 6 inches and leaves room for 15 minutes before removing treated materials from chamber. Operator wears cotton mitts to remove treated materials from sterilizer and place them in aerator; mitts are also placed in aerator. All employees who will operate ETO sterilizer and aerator have thorough in-service training by Central Supply Supervisor. Hospital maintains routine inspection and maintenance contract with AMSCO.	Biomedical and Engineering Shared Technology (BEST) monitored sterilizer in October 1979; BEST reported that facility design and equipment installation is good and room circulation is adequate. Additional data were not available.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators^a	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^c
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^b	Work Practices^c	
New York Site B	AMSCO/ 24/5	12% ETO 88% Freon®	Vented to sewer.	5	Not available.	AMSCO aerators (2) vented to outside atmosphere.	Sterilization conducted in Central Service (36' x 52' x 8'). Mechanical area ventilation with 10 air changes per hour. Direction of airflow is from ETO work area to decontamination area (non-ETO work area).	Access to ETO work area is limited to ETO sterilization workers. At end of cycle, chamber door is opened for 10 minutes before treated materials are removed from chamber. During these 10 minutes, technicians stay out of ETO work area. Technicians wear gloves when removing treated materials from sterilizer and placing them on loader carts. Gloves are discarded after each use. Loader cart is pulled to aerator. Regular in-service training on ETO procedures provided for 1 full-time and 4 rotating technicians. Hospital engineering staff usually inspects equipment on monthly basis.	Monitoring of workplace was conducted with Wilks-Miran gas analyzer. It was discovered that ETO was in the atmosphere during the exhaust to the sewer of the AMSCO Medallion M unit.
	3M (202)/ 2/6	100% ETO	Vented to outside atmosphere.			One post-vacuum. 3M aerator vented to room atmosphere.			

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
New York Site C	Castle (4060)/ 70/3	12% ETO 88% Freon®	Vented to sewer.	2-3	Not available.	Multiple post-vacuum. Chamber equipped with interlock to prevent opening door prior to completion of cycle and with automatic door. Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (50' x 30' x 8'). Rate of air exchanges is 10 air changes per hour. Direction of air-flow is from non-ETO work area to ETO work area.	Access to ETO sterilization area limited to sterilization workers. At end of cycle, operators wear gloves while immediately unloading chamber and pulling cart (containing treated materials) to aerator. Operators receive on-the-job training and view Castle training program on cassettes. These procedures are reviewed with all employees at least yearly and usually more frequently. Regular inspection and protective maintenance performed by outside contractor.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
New York Site D	Castle/ 25/6	12% ETO 88% Freon®	Vented to sewer.	8	Not available.	Chamber equipped with automatic door.	Sterilization conducted in Central Service. (16' x 16' x 11') Mechancial area ventilation with 10 air changes per hour. Direction of air-flow is to ETO work area from non-ETO work area.	Access to ETO sterilization area limited to ETO sterilization workers. At end of sterilization cycle, chamber door is opened 6 inches and the ETO sterilization room is evacuated for 15 minutes. Items transferred to aerator in wire baskets. Operators wear rubber gloves (OSHA approved) and rubber sleeves when transferring treated materials to aerator and wear respirator mask when entering aerator. Employee training is a three step process: new employees receive a documented and formal one-month orientation, then are placed in a "buddy" system (where new employees work along with experienced employees), and finally are placed on a 3-month probationary period. Hospital has contract maintenance program for monthly inspection and service.	Air sampling inspection conducted by OSHA. Found air samples of ETO concentrations to be less than 30 ppm. Hospital has purchased Draeger Model 31 hand model for air sampling; hospital now conducts monthly sampling of sterilizers and aerator.
	3M (400)/ 4/1	100% ETO	Vented to outside atmosphere.		Not available.	Chamber equipped with continuous purge system. Aerator vented to outside atmosphere.			

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
New York Site K	(2) Castle (double door combination steam/ ETO)/ 70/not availabl	12% ETO 88% Freon®	Vacuum exhaust via liquid/gas separator to sewer and atmosphere.	2	Not available.	Pulsating post-vacuum. Liquid/gas separator at drain connected to negative pressure dedicated exhaust system. Pressure relief valve vented to atmosphere. Ball joints installed in ETO gas supply lines to minimize length of line requiring bleeding.	Sterilizer locate between preparation area and clean storage area; each area measures approximately 30' x 30'. Sterilizer equipment area and ETO cylinder storage area enclosed and vented to dedicated, negative pressure exhaust system. Exhaust grilles located at door opening near floo level; direct airflow into equipment area. Rate of air exchange is greater than 10 air changes per hour. Work stations located in preparation area away from sterilizers. Eye wash station located in cylinder storage area.	ETO sterilization conducted only during night shift, wit 1 of 2 operators on duty. At end of cycle, chamber opened immediately and cart is pulled directly to aerator. Operator wears gloves during unloading and transfer operation. Operators undergo training program. In event of leak, operator instructed to leave area and notify supervisor. Sterilization and aeration equipment inspected and serviced under preventive maintenance program.	Monitoring performed by equipment supplier resulted in installed modifications. Weekly spot monitorin performed with Draege colorimetric tubes. Hospital is considering purchase of Wilks-Miran portable IR monitor.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
North Carolina Site A	AMSCO (Medallion)/ 24/1	12% ETO 88% Freon®	Vented to outside atmosphere.	5	Not available.	Pulsating post-vacuum. Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (270 ft^2). Passive area ventilation with 10 air changes in room per hour. Direction of air-flow is towards ETO work area from non-ETO areas.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, chamber door is opened at least 6 inches for a 15 minute period. Workers wear protective gloves when transferring treated materials to aerator from sterilizer. Regular in-service training problems for workers are conducted on ETO process, including safety factors and hazards. Hospital has PMA with AMSCO for inspection and service.	Sample analysis with gas chromatography was performed for hospital by Occupational Health Branch Laboratory (Raleigh, N.C.) Personnel and stationary air samples were collected and indicated minimal worker exposure to ETO during regular ETO sterilization procedures. Levels of ETO detected were <2.0 ppm during personnel sampling, <2.0 ppm during stationary sampling, and 30 ppm at floor level in equipment room approximately 3 inches from ETO sterilizer "drain."

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
North Carolin Site B	AMSCO (Medallion)/ 30/4	12% ETO 88% Freon®	Vented to outside atmosphere	2[e]	Not available.	Not available.	Sterilization conducted in Central Supply. Dimension of ETO work area are 22'6" x 11'6" x 9'. Rate of air exchange in room is 10 air changes per hour. Direction of airflow is up to vents.	Access to ETO work area limited to sterilization workers.	None
	AMSCO (Medallion)/ 30/18	12% ETO 88% Freon®	Mixed with water and exhausted to drain.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Ohio Site A	AMSCO (Cryotherm)/ 6.25/5	12% ETO 88% Freon®	Mixed with water and exhausted to drain.	7	Not available.	Pulsating post-vacuum.	Sterilization conducted in Central Service (6.25 ft^3 sterilizer) and in Surgery (2.25 ft^3 sterilizer) which measure 1600 ft^2 and 300 ft^2, respectively. Each ETO work area has mechanical area ventilation with 10 air changes per hour; the airflow in each work area is to ETO work area from non-ETO work area.	Access to ETO work area in both Central Service and Surgery is limited to sterilization technicians.	None
	AMSCO/ 7.25/15	12% ETO 88% Freon®	Exhausted to outside atmosphere.	6	Not available.	One post-vacuum.			

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Ohio Site 8	(2) AMSCO (Medallion)/ 60/8	12% ETO 88% Freon®	Vented to outside atmosphere.	61^d	Workers wear no protective clothing or equipment. Access to all ETO work areas is not restricted to sterilization workers.	Aerators vented to outside atmosphere through duct work and fan removal.	AMSCO sterilizer: located in Central Supply; work area measures 3000 sq. ft.; mechanical area ventilation (fan) with 3 air changes per hour; airflow directed toward ETO work area. Cryotherm sterilizer: located in operating room; mechanical area ventilation (fan) with 10 air changes per hour; airflow directed toward ETO work area. 3M sterilizer: located in respiratory therapy; mechanical area ventilation (fan). ACMI sterilizer located in urology clinic; dimensions of ETO work area are 12' x 12' x 10'; passive area ventilation with 3 air changes per hour.	In Central Supply, chamber door is opened for 15 minutes (during which time operator leaves room). Treated material transported to aerators (4) in baskets, not by hand. Workers receive on-the-job training in sterilization techniques. AMSCO unit serviced by AMSCO under PMA agreement (quarterly).	Wilks-Miran Analyzer used by safety director on a quarterly basis. Report detection of levels ranging from 3-10 ppm in ETO work area.
	Cryotherm/ 12/11	12% ETO 88% Freon®	Vented to outside atmosphere.	20^e					
	3M (400)/ 4/10	100% ETO	Vented to outside atmosphere.	10^e					
	ACMI/ Table Model/ Not available	100% ETO	Not available.	5^d					

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Oklahoma Site A	AMSCO/ 32/5	12% ETO 88% Freon®	Pulsating vacuum to sewer.	20[d]	No time delay between end of cycle and opening of door. Workers wear no protective equipment.	Three aerators vented to outside atmosphere.	Sterilization conducted in Central Supply area (20' x 12' x 10'). Mechanical area ventilation with 15-20 air changes per hour. Airflow into decontamination area.	Access to sterilization area is limited to ETO sterilization operators. Treated materials (contained in wire basket) placed in aerator immediately after sterilization cycle completed. Workers receive in-service continuous education and on-the-job training in sterilization procedures. AMSCO inspects and conducts maintenance on chambers on a daily basis or as needed.	Monitoring conducted by air tests laboratory. Additional data were not reported.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Oklahoma Site B	AMSCO (Medallion Cryotherm)/ 8/3	12% ETO 88% Freon®	Vented to sewer.	2	At end of sterilization cycle, employee opens sterilizer door and immediately retrieves treated items and transfers them, in a metal basket, onto an aeration cart and into aeration chamber. No protective clothing or equipment worn. Aerator vented to access area behind sterilizers and into the sewer drain.	Multiple post-vacuum. Interlocks to prevent opening of chamber door prior to completion of sterilization cycle. Purge systems at end of cycle.	Sterilization conducted in a work area within Central Sterile Supply. Dimensions of work area are 16' x 20' x 10' and of Central Sterile Supply 64' x 20' x 10'. Mechanical area ventilation with 33.7 per hour in work area and 15.6 in Central Supply. Direction of air-flow is from non-ETO work area to ETO work area.	Access to both ETO work areas is limited to sterilization workers. Workers provided with intra-departmental training upon orientation to department and approximately twice a year after that. Hospital has maintenance contract with AMSCO; also has bio-medical engineer checking venting, air exchanges, and other workplace and equipment designs to be sure hospital is following good hospital practices recommended at ETO workshops.	None
	ACME (OS-10)/ 1.0/7	100% ETO	Dedicated exhaust to outside atmosphere.	11	Aerator vented to access area behind sterilizers and into the sewer drain.	Interlocks to prevent opening of chamber door prior to completion of sterilization cycle. Purge systems at end of cycle.	Sterilization conducted in Respiratory Therapy. Dimensions of ETO work area are 5' x 17' x 8'. Mechanical area ventialtion. Direction of air-flow is from ETO work area to non-ETO work area.		

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Pennsylvania Site A	AMSCO/ 9/15	12% ETO 88% Freon®	Vented to sewer.	3	Three aerators vented to room atmosphere.	Not available.	Sterilization conducted in Central Supply (18' x 14' x 10'). Mechanical area ventilation with 15 air changes per hour. Direction of airflow is towards ETO work area from non-ETO work area. Exhaust fans installed in gas sterilization area.	Access to ETO work area is limited to ETO sterilization workers. At end of cycle, operator opens chamber door and leaves ETO work area for 15 minutes. Treated materials are transferred from sterilizer to aerator by using transfer carriage for large sterilizer and by basket or hand for small sterilizer. Operator wears gloves when removing treated materials from small sterilizer. Gas sterilization and aeration instructions are printed in Central Supply procedure manual. Quarterly inspection and maintenance program is conducted; hospital did not specify who conducts program.	Hospital personnel monitor gas residuals with Draeger gas detector on periodic basis. Maximum levels of 30 ppm to 35 ppm were detected for approximately 15 minutes after opening of sterilizer door.
	AMSCO/ 24/6	12% ETO 88% Freon®	Vented to sewer.			Multiple post-vacuums.			

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{c}
	Equipment Manufacturer/ Size (ft^{3})/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{b}	Work Practices^{c}	
Pennsylvania Site B	3M (400)/ 4/6	100% ETO	Vented to outside atmosphere.	3-4	Not available.	Chambers equipped with interlocks to prevent opening of door before completion of cycle and with additional purge systems.	Sterilization conducted in Central Processing. General work area measures 53' x 29' x 8'. Mechanical area ventilation with 10.3 air changes per hour. Direction of air flow is towards ETO work area from non-ETO work area.	Access to ETO sterilization area limited to ETO sterilization workers. At end of cycle, operator opens door 6 inches for 15 minutes. Operator wears gloves when transferring treated material to aerator. New employees receive in-service education by 3M representative; continued education and supervision provided by group leader. Sterilizers inspected and serviced two times per year.	Emergency Care Research Institute (ECRI) measured ETO levels at hospital in December 1977. ECRI used Wilks-Miran IA General Purpose Infrared Gas Analyzer to monitor. Hospital reports that study indicated no evidence of excessive exposure to personnel; however, in response to report, ventilation in ETO work area was increased from 6.6 to 10.3 air exchanges per hour. No additional data were reported.
	3M (400)/ 4/1	100% ETO	Vented to outside atmosphere.		Not available.	Aerator vented to outside atmosphere.			

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[d]
	Equipment Manufacturer/ Size (ft³)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Pennsylvania Site C	3M/ 2/9	100% ETO	Vented to outside atmosphere.	13	Not available.	Chambers equipped with interlocks to prevent opening of door before completion of cycle. Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (general work area is 60' x 17' x 10'). Mechanical area ventilation. Direction of airflow is from non-ETO work area to ETO work area. Work area equipped with 103 open shelf units.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, operator opens chamber door and waits 15 minutes before unloading chamber. Operator wears neoprene gloves when transferring treated materials from sterilizers to aerator. Items that cannot withstand mechanical aeration are placed on open shelf below large exhaust fan in ETO work area. Operators receive extensive in-service orientation and review programs on ETO procedures. 3M conducts routine maintenance check every 6 months and E.C.R.I. checks equipment annually.	Emergency Care Research Institute has evaluated hospital's ETO aeration process; additional data were not available.
	3M (200)/ 2/10	100% ETO	Vented to outside atmosphere.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
South Carolina	3M/ 3.9/4	100% ETO	Exhausted gas piped to outside atmosphere.	Not available.	Three aerators vented to room atmosphere.	Built in purge system. Interlock to prevent opening door before end of cycle.	Chamber and aerators located in Respiratory Therapy area (14' x 10' x 8'). Mechanical area ventilation with 10 to 12 air changes per hour. Direction of airflow is from non-ETO areas toward ETO area.	Limited access to sterilization area. At end of cycle, chamber door is opened and operator leaves area for 15 minutes. Cotton gloves worn when baskets removed from chamber and placed in aerator. Face masks are available. Workers receive in-house training. ETO chamber cleaned weekly. Maintenance done by Bio-Medical division.	Not available.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Texas	AMSCO (6210A)/ 2/14	12% ETO 88% Freon®	Vented to outside atmosphere.	16	Not available.	Pulsating post-vacuum. Interlocks to prevent opening of chamber door prior to completion of cycle. Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (general work area is 45' x 15' x 12'). Mechanical area ventilation with 7 air changes per hour. Direction of airflow is to ETO area from non-ETO area. Twenty open shelf units.	Access to ETO sterilization area limited to sterilization workers. At end of cycle, chamber door is partially opened. Operator waits 15 minutes before transferring treated materials from sterilizer to open shelves. Operator wears cotton gloves. Operators receive periodic in-service training on operation of sterilizer and transfer of treated materials to aerator. Sterilizer checked at least every 3 months by "factory" trained repairman.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Virginia Site A	AMSCO/ 8/Not available	12% ETO 88% Freon®	Vented to sterilizer maintenance room.	7	Aerator vented to sterilizer maintenance room.	Multiple post-vacuums. Chamber is equipped with interlocks to prevent opening of door before end of cycle.	Sterilization conducted in Central Supply. Mechanical area ventilation with 10 air changes per hour. Direction of airflow is to non-ETO work areas from ETO work area.	Access to ETO work area limited to ETO sterilization workers. Operators follow AHA guidelines for ETO sterilization procedures. Treated materials transferred to aerator on cart. Operators wear gloves. New employees are told of principles, procedures and hazards of ETO before they are allowed to operate sterilizer or aerator. These instructions are reviewed yearly. Hospital makes quarterly preventive maintenance checks.	Facility was monitored by a private company using Wilks-Miran 1A General Purpose Infrared Gas Analyzer. TWA reported for one sterilization cycle was 3 ppm; the worst-case estimated short-term exposure level was 27 ppm.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Virginia Site B	Castle (1500)/ 2/2	12% ETO 88% Freon®	Not available.	1	Operating room personnel may, on occasion, come to ETO work area to pick up supplies. There is no regularly scheduled program of equipment inspection and maintenance. Aerator (Castle 1550) exhausts to room atmosphere.	Not available.	Sterilization conducted in separate room off of Central Supply. Mechanical area ventilation with 20 air changes per hour. Direction of airflow is into general building air circulation.	Access to ETO work area is generally limited to ETO sterilization worker. At end of cycle, operator opens door and leaves room for 5 minutes before unloading treated materials from sterilizer to aerator (materials aerated for approximately 6 hours or overnight). Castle provided in-house demonstration of how to use ETO equipment; however, hospital reports that Castle representative did not stress employee safeguards to prevent exposure to ETO.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Washington Site A	AMSCO/ 9/5	12% ETO 88% Freon®	Not available.	14	Not available.	Chamber equipped with interlocks to prevent opening of door prior to completion of cycle. Aerator vented to outside atmosphere.	Sterilization conducted in Central Service (128 ft^2). Mechanical area ventilation with 12 air changes per hour. Direction of airflow is towards ETO work area.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, chamber door is opened 6 inches for 15 minutes before treated materials are removed. Operator wears gloves when transferring treated materials to aerator from sterilizer. AMSCO salesman explained to employees workings of sterilizer and aerator and precautions to be taken when using ETO. Central Supply workers are provided with procedure book and ETO file containing use guidelines. New literature and information from seminars on ETO use are reviewed with workers. Hospital has preventative maintenance program with an outside firm for monthly inspection and service.	Hospital central service area was monitored to measure employee exposure to ETO in March 1979 and March 1980 by Dept. of Environmental Health, University of Washington. March 1979 survey: Samples were collected on activated charcoal and analyzed by gas chromatography as recommended by Quazi Ketchum method. This survey did not detect any concentrations of ETO on top of sterilizer, on floor in back of sterilizer in separate room, across room from sterilizer, and on main work bench. March 1980 survey: Samples were collected using low-flow pumps and activated carbon adsorption tubes. This survey detected ETO levels of 2.7 ppm in Central Supply above sterilizer, and no concentrations of ETO at Central Supply on table in middle of room or at Central Supply on bench 10 ft. from sterilizer.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Washington Site A (Concluded)									It should be noted that the Washington State Industrial Safety and Health Act has set permissable exposure level (PEL) for ETO at 50 ppm. The PEL refers to the concentration a person may be safely exposed to 8-10 hours per day within a 40-hour week without adverse affects to health.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Washington Site 8	AMSCO/ 48/4	12% ETO 88% Freon®	Vented to outside atmosphere.	13	Not available.	Multiple post-vacuums. Aerator vented to outside atmosphere.	Sterilization conducted in Central Supply (20' x 8½' x 8'). Passive area ventilation with 10-12 air changes per hour. Direction of airflow is towards ETO work area.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, chamber door is cracked open 6 inches and the area is vacated for 15-20 minutes while ETO gas dissipates. Operator wears latex gloves and scrub suit to pull sterilizer cage out of chamber and place directly into aerator (so that none of the treated materials need to be handled). ETO work procedures and training are updated as new recommendations are made by A.A.M.I., and other groups. Operators receive 4-to 6-week training program covering all areas of sterilization. Hospital has preventive maintenance agreement with AMSCO for bimonthly inspection and service.	None

TABLE C-1 (CONTINUED)

	Sterilization/Fumigation Equipment					Control Measures Implemented			
State/ Site	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System	Total Number of Operators[a]	Potential Exposure Situations	Equipment Design	Workplace Design[b]	Work Practices[c]	Monitoring of Workplace for Residual Levels of ETO[d]
Washington, D.C.	(3) Castle/ 12, 18. <12/ <2	12% ETO 88% Freon®	Vented to drain.	8-9	Access to ETO sterilization area is not restricted to sterilizer operators.	Pulsating post-vacuum. Aerators vented to outside atmosphere through dedicated exhaust.	Sterilization conducted in Central Supply. Ceiling exhaust vents located above loading door, unloading door and recessed equipment area. Direction of air-flow is from non-ETO to ETO work area.	At end of cycle, operator opens door for 15 minutes before unloading treated materials from chamber. Operators transfer treated materials in baskets to (4) aerators. Operators wear cotton gloves and goggles. Gloves are placed in aerator after use. Operators receive in-house training in ETO sterilization techniques. Equipment undergoes monthly inspection and maintenance. Medical examinations have been performed on all 32 personnel (ETO sterilizer operators, maintenance personnel, and monitoring personnel) in Central Supply.	Hospital monitored ETO work area to evaluate effectiveness of pulsating post-vacuum modification to 2 Castle chambers, using Wilks-Miran 103 infrared gas analyzer at 6 inches from sterilizer door and at shoulder height. Immediately upon door opening, peak ETO concentrations were 18 ppm. Within 7 and 15 minutes, levels had dropped to 15 ppm and 3 ppm, respectively. Other changes made to equipment as a result of data obtained from monitoring include sealing of the drain and venting of gas through a dedicated exhaust to the outside atmosphere and installation of a reducer in the exhaust line to slow the rate of water released from the chamber.

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Wisconsin Site A	3M (202)/ 2/2	100% ETO	Vented through copper tube to outside atmosphere.	6	Not available.	Two aerators vented to outside atmosphere.	Sterilization conducted in sterilizer room of Central Service. Sterilizer room measures 19'3" x 8' x 8'. Mechanical area ventilation with air movement of 750 cfm.[f] Direction of air-flow is to ETO work area from non-ETO work area.	Access to ETO sterilization room limited to ETO sterilization workers. At end of cycle, chamber doo is cracked open for a 10-minute period before treated materials are removed. Operator wears disposable latex exam gloves when transferring treated materials (i sterilizer basket) from sterilizer to aerator; if ambient aeration is required, treated materials are placed on counter top away from main work area where they remain undisturbed for 1 week. Workers receive orientation training and yearly review which focus on task mastery of sterilization and aeratio procedures. Hospital has preventive maintenance contract with 3M for both sterilizers and aerators.	Hospital's Director of Building Services and a laboratory toxicologist monitor ETO work area every 6 months. Draeger Model 31, V-100 cm^3 with Athylenoxide 25/a tubes, used to monitor ETO levels at the door of the sterilizer as it is opened at the completion of a cycle; hospital reports that gas levels were below the "measurable amount." Additional data were not supplied.
	3M (400)/ 4/3	100% ETO	Vented through copper tube to outside atmosphere.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^{3})/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
Wisconsin Site 8	AMSCO (65GM)/ 36/4	12% ETO 88% Freon®	Vented to outside atmosphere.	3	Access to ETO sterilization area is not limited to sterilization workers and includes general hospital personnel.	Multiple post-vacuums. Chamber equipped with interlock to prevent opening of door prior to completion of cycle. Aerator vented to outside atmosphere via duct work.	Sterilization conducted in Central Supply (27' x 21' x 18'). Mechanical area ventilation with 10 air changes per hour. Direction of airflow is from non-ETO area to ETO area.	At end of cycle, door is opened about 3 inches for 20 minutes before treated materials are removed. Operators wear cloth gloves when transferring treated materials (in basket) from sterilizer to aerator and when removing treated materials from aerator and placing on open shelf units. Sterilization workers receive in-service program on ETO procedures for 3 months and operating instructions in a policy and procedures work book, and can find list of procedures to deal with equipment malfunctions posted next to sterilizer. Sterilizers are checked daily (in-house) and Plant Operations exchanges all tanks and monitors all ETO lines daily.	None

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
State not labeled Site A	AMSCO/ 12/14	12% ETO 88% Freon®	Vented to outside atmosphere.	2	Not available.	Overhead hoods located above sterilizers. Aerator vented to outside atmosphere.	Sterilization conducted in corner of Central Supply. Central Supply measures 20' x 5' x 10'. Direction of air-flow is towards ETO work area.	Access to ETO work area limited to sterilization workers. At end of cycle, chamber door is cracked open and personnel avoid ETO work area; operator waits 15 minutes before unloading chamber. Operator wears cloth gloves when transferring treated material from sterilizer to small cart to aerator. Personnel required to take in-service training before they are allowed to use ETO sterilizer. Review sessions on ETO procedures held every 6 months. Hospital contracts with AMSCO for regularly scheduled program of equipment service and maintenance.	As of August 1980, Central Supply area was being renovated. In October 1980, new work area will be monitored.
	AMSCO Eagle/ 12/<1	12% ETO 88% Freon®	Vented to outside atmosphere.						

TABLE C-1 (CONTINUED)

State/ Site	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[c]
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[c]	
State not labeled Site B	Castle (4060)/ 60/5	12% ETO 88% Freon®	Vented to sewer drain and to atmosphere.	1	There is no regularly scheduled program of equipment inspection and maintenance.	One post-vacuum. Chamber equipped with automatic doors; interlocks to prevent opening of chamber door prior to completion of cycle; and initiated procedure to abort cycle. Additional purge cycles are budgeted for installation. Liquid/gas separator at sewer drain. Two aerators vented to outside atmosphere.	Sterilization conducted in Central Supply. Sterilizer entry area measures 27' x 33' x 9'; sterilizer exit area measures 33' x 48' x 9'. Passive area ventilation with 6-10 air changes per hour. Direction of airflow is from ETO work area in sterilizer entry area and to ETO work area in sterilizer exit area. Hooded area above sterilizer doors vented to outside atmosphere.	Access to ETO work area limited to ETO sterilization workers. At end of cycle, door is automatically opened and any residual chamber gases are allowed to vent to hood above sterilizer for approximately 10 minutes. Operator wears cotton gloves when removing carts from sterilizer and placing them into aerator (approximately 6 ft. away). In-house training programs offered each year. On-the-job training includes literature from AAMI and ASHCSP standards for E.O. in hospitals and attendance at outside seminars conducted by AMSCO, ASHCSP, IAHCSP, and CCST.	Hospital safety department used Wilks-Miran Vapor Analyzer to monitor sterilizers. Only specific problem noted in 5 years is possibility of gas leakage during pressurization at beginning of sterilization cycle. This is monitored with Draeger gas detector. Periodically monitor area around open door at completion of cycle.

TABLE C-1 (CONCLUDED)

[a] Refers to the total number of persons authorized to operate ETO sterilization equipment at this facility unless otherwise indicated.

[b] Where indicated, the dimensions of ETO work areas represent length x width x height.

[c] Data in this column apply to all ETO sterilizers, ETO work areas, or ETO sterilizer operators at this facility.

[d] The total number of operators reported by this facility may include general hospital personnel or other employees in the ETO work area.

[e] The total number of operators reported by this facility represents the number of operators per shift.

[f] This represents cubic feet per minute (cfm).

TABLE C-2

PRACTICES RELATIVE TO WORKER EXPOSURE AT
SELECTED MEDICAL PRODUCTS INDUSTRY SITES

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site A	(2) 1200	12% ETO 88% Freon®	Vented to outside of building.	1-4	Operators must enter chamber to unload treated materials. Access to ETO sterilization area is not limited to ETO sterilization workers; other personnel may be in ETO work area.	Chamber equipped with positive pressure air wash which operates prior to opening of chamber.	Sterilization conducted in 25,000 ft^2 general warehouse with 30 ft. high ceilings. Mechanical area ventilation (fans). Rate of air exchange is 1000 cfm.[d] Direction of air-flow is towards ETO sterilizer pit.	Operators wear gas masks when unloading chamber. Operators receive briefings on procedures to be utilized in sterilization process. Regularly scheduled program of equipment inspection and maintenance, including sterilizer validation.	Work area monitored for environmental levels of ETO using gas chromatography. In response to data obtained from such monitoring, use of gas masks was initiated and the period of air wash was lengthened. Less than 1 ppm per day has been detected with gas chromatography monitoring since controls have been implemented.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site 8	115	12% ETO 88% Freon®	Vacuum pump exhaust through roof.	1-4 (Operators are responsible for loading, gassing, venting, purging, and unloading the sterilizers).	Operators must enter large sterilizer to unload treated materials.	Each sterilizer performs 2 air purges and 1-hour continuous purge before opening of chamber doors. 115 ft^3 sterilizer equipped with gasketed double door. 32 ft^3 sterilizer equipped with gasketed door. Aerators, used for treated materials from small sterilizer, are exhausted to outside atmosphere.	115 ft^3 sterilizer, treatment is conducted in a separate work area (20' x 17' x 12') equipped with 10 air changes per hour. 32 ft^3 sterilizer, treatment is conducted in the general work area (50' x 12' x 8') equipped with 8 air changes per hour. In each area, there is mechanical area ventilation and the direction of airflow is towards ETO area from non-ETO area. Aeration room has its own air system; makeup air is outside air and exhaust is to atmosphere.	Access to ETO sterilization area restricted to authorized personnel. At end of cycle, chamber door is cracked open and personnel leave area for 30 minutes. Operators wear goggles and gloves when unloading sterilizers. Treated materials are placed on stainless steel carts and moved to aeration room or aerator. Large sterilizer opens to aeration room. Workers are trained by supervisors on operation of equipment and loading and unloading. Supervisors also oversee unloading procedures of new workers for several weeks before new workers are allowed to operate equipment on their own. Equipment is inspected and maintenance work is performed every three months. Instruments are recalibrated if necessary.	Personnel monitors have been used on employees during unloading process. Chambers have been analyzed for ETO content after purging but before opening. Treated materials have been analyzed for residual ETO with gas chromatography. Monitoring data were not reported.
	32	12% ETO 88% Freon®	Vacuum pump exhaust through room.						

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{b}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{b}
	Size of Sterilizer (ft^{3})	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{b,c}	Work Practices^{b}	
Site C	1100	12% ETO 88% Freon®	Vented to outside atmosphere.	1-4 (Operators load and unload chamber, monitor cycle, and retrieve biological indicator samples from load).	Operators must enter chamber to retrieve treated materials. Treated materials are manually pushed on rollers to front of chamber. Workers do not wear protective clothing when unloading chamber.	Two post-vacuums and 1 air wash drawn. Site reports that chamber is a self-contained unit and that complete aeration occurs prior to removal of treated material from chamber.	Sterilization conducted in general work area (100' x 50' x 40'). Passive area ventilation. Direction of air-flow is both to and from ETO work area.	There is limited employee traffic in sterilizer area. At end of cycle, chamber door is opened 6 inches for approximately 15 minutes. After this period, door is completely opened and treated materials are retrieved. Lift truck used to transport treated material to storage area. Workers are trained on all procedures to be utilized in sterilization process and are informed of potential medical problems that result from ETO exposure. Inspection and maintenance program is outlined in a formal procedure. Monthly checks and maintenance are performed on door bearings and gasket, recorder pens, vacuum pump seals, and blow down strainers. Semi-annual checks and maintenance performed on sterilant filters, humidity sensors, valves, internal paint, circulating pump, and air in-bleed filter. Annual checks and maintenance performed on ball valves, sterilant valves, relief valves, pump motors and vacuum pump.	Monitoring has been performed to determine worker exposure to ETO during normal sterilizer operation. Levels below 10 ppm were detected with gas chromatography.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site B	Not applicable.	100% ETO -------- 12% ETO 88% Freon® II	Not applicable	1-4	Employees must enter aeration room (for short periods of time).	Sterijet® system used to treat materials. Sterijet® equipped with built-in cabinet exhaust capable of maintaining minimum operator exposure (typically 5 ppm or less).	Sterilization conducted in work area (13' x 7' x 7'). Mechanical area ventilation. Rate of air movements is 2000 cfm.[d] Direction of airflow is from non-ETO areas towards ETO areas. Aeration room vented to outside atmosphere.	Materials moved to aeration room on conveyor and then stored in stacked cardboard boxes. Operator work practices governed by written procedures in accordance with Good Manufacturing Practices recommended by U.S. FDA. No formal classroom worker training program; however, training is conducted by supervisors on the job and monitored by a bacteriologist. There is a regularly scheduled program of equipment inspection and maintenance in compliance with FDA mandated Good Manufacturing Practices. Written test procedures and inspection and maintenance requirements are monitored by computer generated operation sheets. Sheets are logged into computer when inspection and maintenance is completed. Audit procedures assure review of completed operation sheets.	Miran 101 Infrared monitors are used to confirm ETO levels of employee exposure, sources of ETO which may be released into the workspace, and improvement in facilities. Gas chromatography also used. ETO concentration in aeration room is typically 30 ppm (with employee exposure less than 1 hour per day, about 2 to 3 days per week). Over past several years levels of worker exposure have been reduced from more than 100 ppm on occasion to typically below 10 ppm.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site E	400	12% ETO 88% Freon®	Vented to atmosphere; vacuum to water bath.	7	Workers must enter sterilizer to retrieve treated materials.	All 3 sterilizers exhaust to outside Wilkes sensors. 400 ft^3 and 700 ft^3 sterilizers equipped with interlocks to prevent opening of chamber door before completion of cycle. Rear exhaust in these 2 sterilizers is approximately 1000 cfm.[d]	400 ft^3 and 700 ft^3 sterilizers, treatment is conducted in room (30' x 30') equipped with 43 air changes per hour. 1300 ft^3 sterilizer, treatment is conducted in a separate room (12' x 75') equipped with 30 air changes per hour. In each ETO area, there is mechanical area ventilation and the direction of airflow is from ETO area negative to surrounding area. Floor ventilation located directly under chamber doors. Treated materials stored in unoccupied warehouse area.	Access to ETO sterilization areas is semirestricted. At end of cycle, door is opened 6 inches for 15 minutes, then fully opened for another 15 minutes before treated materials are retrieved. Workers retrieve materials by pallet load with pallet jack. Workers wear goggles and gloves when changing gas cylinders. Respirators are available in event of a spill. Workers receive formal training program which includes manual and video cassettes. Formal written maintenance program exists for daily, weekly, monthly, and annual preventive maintenance.	Sterilizer areas monitored 24 hours per day using Wilks 12 point IR unit. Employee air samples are taken every 6 months at breathing zone using air pumps. Facility reports that levels are <10 ppm except for chamber entry, which is 25-45 ppm. Procedure and process changes have been made in past 2 years in response to data obtained from monitoring. Latest changes include interior ventilation during unloading process and post conditioning chambers.
	700	12% ETO 88% Freon®	Vented to atmosphere; vacuum to water bath.						
	1300	12% ETO 88% Freon® 100% ETO	Pulsing steam ejector to outside atmosphere.						

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site F	195	12% ETO 88% Freon®	Vacuum system to water system.	1-4	Operator must enter chamber to remove product load.	External exhaust located at front and rear of chamber; exhausted to outside atmosphere. Internal exhaust system at rear of sterilizer. Sterilizer equipped with vacuum system connected to recirculation water system.	195 ft^3 sterilizer is located in a separate room (14' x 36' x 20') with air exchange of 1200 cfm[d]. 540 ft^3 sterilizer is located in a separate room (32' x 27' x 14') with a rate of air exchange of 1200 cfm.[d] In both ETO work areas there is mechanical area ventilation (circulation fan) and the direction of airflow is from ETO work area to non-ETO work area.	Access to ETO work areas is restricted to authorized personnel. At end of cycle, a check is made to ensure that all exhaust systems are turned on and operating. Then sterilizer door is opened 12 inches and a minimum wait period of 5 minutes is utilized before the door is fully opened to unload the treated materials. Operators wear respirators when unloading chambers (and changing gas cylinders). Treated loads are immediately placed in aeration room. Worker training includes complete training for compliance to good manufacturing processes and safety, training films, on the job training, and safety films. Equipment inspection and maintenance includes checks of respirator before each use, of recirculation pump every 6 months, of vacuum pump every 6 months, of door gasket on opening chamber door, and of humidity sensors every 3 months and replaced every 6 months (4 sensors rotated for use); and change of bacterial air filter every 6 months and of gas filters every 2 months.	Environmental monitoring data is collected using Miran 103 Vapor Analyzer (Miran 1A Analyzer is on order for additional monitoring). In response to data obtained from past monitoring, exhaust and ventilation have been improved for sterilization chamber and aeration room. With additional ventilation capacity and procedural changes, monitoring has indicated a reduced level of exposure to ETO.
	540	12% ETO 88% Freon®	Vacuum/rear water system to outside cooling tower. Rear 10" mechanical exhaust vent to outside atmosphere.						

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site C	696	12% ETO 88% Freon[e]	Water sealed vacuum pump exhaust through water separator, vented to sewer.	3 (responsible for complete sterilizer operations, including loading, operation and monitoring of cycle, and unloading treated material from chamber).	Operators must enter chamber to retrieve treated materials.	Multiple post-vacuums (2 are being drawn at present). Jacketed chamber with recirculating blower system. Water effluent to sewer drain located next to chamber. Vapor exhaust to outside atmosphere. Rectangular horizontal sliding chamber door is gasket-sealed.	Sterilization conducted in 1080 ft^2 area located within restricted warehouse aeration area. Ventilated by use of 2000 cfm[d] mechanical exhaust system. Rate of air exchange in sterilizer area is 4.6 air changes per hour. Direction of air flow is from ETO to non-ETO area. Warehouse-type aeration area is ventilated by mechanical and passive airflow exhausted to atmosphere.	Access to ETO work area is restricted to authorized personnel. At end of cycle, front and rear sterilizer doors are opened and exhaust fan is activated for 20 minutes prior to removal of material. Forklifts are utilized to place pallets on racks for 10-day aeration period. Operators provided with Wilson air-line respirators and gloves. Circulated periodicals and scripts pertaining to safe handling of ETO and sterilization techniques are routed to and read by all operators. Formalized ETO training procedure is being implemented. Procedures are followed prior to each cycle which include inspection of critical areas. Preventive maintenance schedules are enforced and recorded.	Monitoring is in progress at present (August 1980) using charcoal tube analysis by gas chromatography, Draeger gas detector tubes, and IST sensor. Site reports that although data are not available at present, ventilation is being improved and training increased.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site H	300	12% ETO 88% Freon®	Vented to sewer drain.	1-4 (responsibilities include loading and unloading, cycle control process instrumentation and documentation).	Not available.	Chamber equipped with double door and o-ring type gasket, and is evacuated with Sihi water-ring pump. Exhaust line is heat traced and removed from chamber. Vent line is external to building and located about 60 feet above grade level. Chamber is vented to 0 psig[e] and pumped down to at least 25" Hg vacuum, followed by a 1 to 8 hour air wash cycle. Interlocks on chamber door prevent gas charging of chamber without proper sealing of door.	Sterilization conducted external to main building. Sterilizer area is 40' x 20' x 12' and is covered. Natural ventilation supplemented with forced air exhaust. Rate of air movement is ≥200 cfm.[d] Sterilizer area is heavily alarmed for ETO detection. Aeration room is heated and vented with forced air exhaust to outside of building.	Access to ETO work area is restricted to authorized personnel (less than 4 personnel). Wherever possible, chamber door is left open overnight (in accordance with local pollution abatement laws) prior to unloading. Operators wear air-supplied respirators and gloves during unloading. Operators must comply with all written operating and safety procedures. All procedures are documented, including safety procedures. Workers are college educated in science or engineering and are made aware of ETO dangers. Complete preventive maintenance program is in place. All inspections and maintenance are documented.	Environment has been monitored for levels of ETO by using gas chromatography, charcoal tube personnel monitors, IR (Wilks Miran), and specially calibrated hydrocarbon detectors. The monitoring protocol was conducted in 1978 by Health Industry Manufacturers Association as submission for RPAR rebuttal. In response to data obtained from monitoring, air-supplied respirators were installed to be used during unloading operations. Follow-up monitoring has detected ETO levels of less than 1 ppm.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design[b]	Workplace Design[b,c]	Work Practices[b]	
Site I	750	12% ETO 88% Freon®	Vented via pipe to outside atmosphere.	1-4	Workers may have to enter sterilizer when treated product expands and cannot be removed through normal procedures. Sterilization and ventilation areas are not restricted, but only personnel associated with sterilization are in that area.	One post-vacuum. Each sterilizer equipped with gasket seal.	For first 750 ft^3 sterilizer, treatment conducted in warehouse (200' x 100' x 18'); for (2) 140, 250, and 1000 ft^3 sterilizers in warehouse (460' x 105' x 17'); and for other 750 ft^3 sterilizer in (140' x 84' x 18') general work area. All 3 ETO work areas have mechanical area ventilation and the direction of airflow is from ETO work area to non-ETO work area. Room vents exhaust to outside atmosphere.	At end of cycle, chamber is allowed to aerate for minimum of 15 minutes before removal of treated material. Treated material is skidded and transferred by hand pallet truck. Workers receive on-the-job training. Sterilization equipment periodically checked by in-house personnel (and manufacturers if required).	Monitoring conducted by outside consultant. Facility reviewing in-house testing. Monitoring data not available.
	(2) 140 250 1000	12% ETO 88% Freon®	Vented via pipe to outside atmosphere.						
	750	12% ETO 88% Freon®	Vented via pipe to outside atmosphere.						

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site J	1000	12% ETO 88% Freon®	Exhausted to enclosed sewer drain and exhaust fan and stack.	1-4 (Operator required to stage product, complete documentation, check condition of sterilizer, and verify that all adjustable mechanisms are set to specified parameters.	Access to ETO sterilization area is not restricted to the 1-4 operators. An additional 3-8 employees (including microbiologists, maintenance mechanics, supervisors, quality control inspectors, and engineers) may come into indirect, inconsistent, or peripheral contact. Operators must enter sterilizer for short period of time to manually unload treated lots.	Chamber manufactured by Beverly Pacific. Two post-vacuums. Chamber door equipped with interlocks and is hydraulically tightened. Chamber equipped with leak alarm.	Sterilization conducted in new warehouse facility which has central fan system, a rate of air exchange of 20 air changes per hour, and direction of air flow is vertical. Guard fence around Vacudyne chamber, primarily for equipment protection. Aeration areas (designated as sterilized product-only area) located near sterilizer.	At end of Beverly Pacific 1000 ft^3 chamber cycle, doors are automatically cracked (following double-vacuum airwash) and double recirculating blowers are activated for 1 hour before treated materials are removed from chamber. At end of Vacudyne Altair 450 ft^3 chamber cycle, doors are manually cracked 6-8 inches (following air wash) for minimum of 20 minutes before treated materials are removed. Treated materials are transported on pallets by battery operated fork truck and hand trucks. Operators are required to wear protective goggles while changing 12/88 cylinders. Operators receive personal instruction from supervisors only, including written materials on function and theory, component systems, drawings, safety, copy of procedures, required documentation, and written and oral testing.	There is specific Standard Operating Procedure which addresses Vapor Environmental Monitoring for each sterilizer located in its respective sterilization area. Wilks-Miran 101-ETO Vapor Analyzer was used for analysis. All readings accumulated since monitoring began have fallen under maximum allowable OSHA limits set for ETO vapors. Changes have been made by installing ventilation system and implementing training program for proper procedural handling and associated work practices for dealing with use of ETO gas for sterilization of product. Subsequent ETO vapor analysis after implementation of changes mentioned above.
	450	12% ETO 88% Freon®	Exhausted to enclosed sewer drain.			Chamber manufactured by Vacudyne Altair. One post-vacuum. Door equipped with leak alarms. Door equipped with leak alarms.			

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of EtO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site J (Concluded)								All equipment subject to visual inspection prior to every cycle for correct valve settings, gauge readings, parameter conformity, and general condition of all equipment which is reported immediately to supervisor or maintenance personnel. Preventative maintenance program currently being devised.	Indicate a continued safe environmental working condition; however, a detailed evaluation to determine to what degree worker exposure has been reduced has not been initiated.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site K	520 634 1280	12% ETO 88% Freon[e]	Vented to storm sewer and outside atmosphere.	3	Operators must enter chamber to retrieve treated materials.	Multiple post-vacuums to storm sewer plus water separator for exhausting into atmosphere at height of approximately 45 feet above ground level. Sterilizers equipped with vacuum pump which draws ambient air into chamber to vent/dilute sterilant gas still in chamber. Upon opening of door, 2300 cfm[d] exhaust blower (which is connected to grate-covered pit in front of sterilizer) exhausts sterilant gas which may be emitted from the chamber. Exhaust outlets are above and away from any factory/office air intake sources.	Sterilization conducted in warehouse (200' x 200' x 37'). Warehouse fitted with 3 turbine roof ventilation fans 200 cfm[d] each which cap vent stacks on roof of warehouse and with 4 ceiling fans (1) 9000 cfm[d] (2) 26,500 cfm[d] (1) 18,000 cfm[d] Rate of air exchange is 10 air changes per hour. Direction of airflow is towards ETO work area and away from non-ETO areas.	Sterilization area is restricted to ETO workers and maintenance personnel. At end of cycle operator opens door 6 inches. Operator presses cycle start button which starts vacuum pump (see equipment design). At the end of these actions, operator leaves ETO area for 10 minutes. At the end of this time period the operator returns, opens the door completely, and again leaves the area for 10 minutes. In moving material from chamber to sterility-hold area, operator operates fork lift from front and so that any remaining gas in product will trail behind operator. Workers provided with company-purchased clothing. Meetings are held periodically for experienced workers by Production General Foreman to discuss both old and new procedures. New workers are indoctrinated and trained by experienced operators. As new procedures	Samples of ETO vapors have been collected by drawing ambient area air through Qual and Ketchum tubes. Charcoal tubes of system were attached to employee near breathing zone. Pumps were calibrated prior to any tests using bubble meters (±0.01 L/Min.) Samples collected were analyzed at A.I.H.A. accredited lab (National Loss Control Service Corp.) using NIOSH procedure S286. Additional data was not reported.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situation[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site K (Concluded)						Treated materials are on wooden pallets which roll on ball-bearing rollers, making them easily movable. Ease of movement allows for minimum worker exposure to residual gas. During removal of treated materials, vacuum pump is operating and continues to exhaust gas from bottom of chamber. Chamber door can not be accidently closed because "self-operating" stop prevents door closure. Also available to operator inside chamber are pull cords to shut off all power, to open vent valves, and to activate alarms.		and/or good manufacturing practices are developed, they are posted on bulletin board at sterilizer units. Preventive maintenance (P.M.) program is established through use of addressograph plate system. Plates are automatically fed monthly into sorting system which designates P.M.'s for any specific month; plates are then put into printing unit which stamps out work order. On daily basis, plant engineer reviews process chart of each unit and then visually inspects controls and process parameters of each unit.	

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^a,b	Potential Exposure Situations^b	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^b
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^b,c	Work Practices^b	
Site L	1500	12% ETO 88% Freon® - - - - - - 100% ETO	Vented to outside atmosphere	3-8	Workers must enter the chamber to retrieve treated materials. Materials are aerated in an open space of warehouse with no special ventilation.	Multiple post-vacuums. Chamber equipped with water sealed vacuum pump, with water recycled through outdoor cooling tower. Sterilizer can be programmed to perform up to 3 post-vacuums. 400 cfm^d of air is purged through the second and third sterilizers and discharged outdoors. Chamber sealed with 6 manual clamps and rubber gasket. Chamber equipped with roller conveyors.	One 1500 ft^3 sterilizer located in a separate room (76' x 11'6" x 22') that has mechanical area ventilation; a rate or air movement of 1480 cfm^d and in which the direction of airflow is from the ETO work area to outside atmosphere. For second sterilizer, treatment is conducted in general work area (80' x 13' x 18') with passive area ventilation. For third sterilizer ETO work area dimensions were not reported; however, the area has mechanical ventilation, a rate of air movement of 1200 cfm^d and the direction of airflow is from ETO work area to the outside atmosphere. Additional ventilation will be added in work area and aeration area.	Access is limited to sterilization workers and material handlers. At the end of cycle, chamber door is left open for 15 minutes before treated materials are removed. Sterilized items are removed by fork lift truck and transferred to warehouse. Operators wear face shield and gloves when handling gas containers. Operators receive instruction on the operation of sterilizer, safe handling of gases, and emergency procedures. Regular maintenance is performed, which includes maintenance of components, leak testing, and calibration of controls.	Monitoring for environmental levels of ETO using gas chromatograph (NIOSH method S286) has been conducted inside the sterilization and the aeration area. Monitoring data were not made available.
	1500	12% ETO 88% Freon®	Vented to outside atmosphere						
	1500	12% ETO 88% Freon®	Vented to outside atmosphere	5					

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft³)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site N	810	12% ETO 88% Freon®	Pulsing vacuum to outside of building.	1-4	Not available.	Chamber manufactured by Vacudyne Altair.	ETO work area is (6' x 6' 22.3'), located in large warehouse equipped with large ceiling fans. Three air wash cycles.	Access to sterilization and quarantine areas restricted to authorized personnel. Recently instituted a 15-minute time delay between first opening of chamber door and retrieval of sterilized items. Treated materials removed with hydraulic hand truck and placed in quarantine area. Operator pulls hand truck. Operator wears gas mask and gloves. Operator given complete written instructions for operation of sterilizer and receives training and guidance from foreman. Regularly scheduled program of equipment inspection and maintenance. Documentation of program available at sterilizer and in Master Device Record. Treated material aerated in quarantine area for 10-14 days, and then may remain in storage shelves for up to 3 years.	None

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft³)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b,c]	
Site K	1300	12% ETO 88% Freon® - - - - - - 100% ETO	Vented to atmosphere.	2	Treated materials removed from chamber immediately at end of cycle; no time delay at end of cycle.	Chamber manufactured by Vacudyne Altair. Two post-vacuums. Valves allow chamber recirculation system to purge chamber. Gas separated out of recirculating water system and vented to roof. Microcomputer programs chamber for treatment cycle; sounds buzzers if problem occurs and can abort cycle if necessary.	Chamber door opens to warehouse area; however, chamber is isolated by explosion-proof door and concrete block walls (1 ft. thick). 12/88 and 100% ETO tanks are segregated from each other and from sterilizer. Fan (5' x 4') in ceiling at end of warehouse opposite sterilizer operates continuously.	Treated materials are stored in warehouse for 14-15 days. Operators use propane-powered forklift to load and unload chamber rapidly (taking approximately 15 minutes). Operators wear gloves and face shield when changing cylinders; safety shower located in equipment area; oxygen supplied respirator available in case of emergency. Warehouse doors near sterilizer left open while sterilizer in operation. Operator received 2 weeks of training from Vacudyne. Operator uses bronze wrenches when changing ETO tanks to prevent sparks.	Lower explosion limit sensors (manufactured by Mine Safety Appliance Company) in area around chamber and in tank storage area. Additional data not available.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft³)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site O	1023	12% ETO 88% Freon®	Vented to outside atmosphere.	2	Access to ETO work area is not restricted to ETO sterilization workers. Sterilizer located near general walk way; therefore, other workers may be exposed to ETO.	Four air washes performed (each lasting 15 minutes) at end of exposure cycle. Sterilizer manufactured by Vacudyne/Altair.	Sterilization conducted in large warehouse. Two large fans run continuously at opposite ends of warehouse.	At end of cycle, chamber door is opened for 3 to 4 hours or overnight before treated materials are removed. Treated materials are placed in fenced quarantine area for 14 days. Operator received training at previous job experience. Site has service contract with private firm, but follows Vacudyne schedule for parts replacement. Sterilizer is checked every 2 weeks for leaks around gaskets, piping, and area around ETO cylinders.	None

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b]	Work Practices[b]	
Site F	(2) 673	12% ETO 88% Freon®	Vented to atmosphere.	Not available.	Not available.	Chamber equipped with pulsing vacuum and multiple air washes, which are vented to 10 feet above highest roof elevation; 3 water seal vacuum cycles; and gasket seals. Roof vents located more than 60 feet from nearest HVAC unit.	Sterilization conducted in room measuring 60' x 30' x 14'. Mechanical area ventilation. Air movements controlled by fan with dual speeds of 1240 cfm[c] and 1380 cfm.[d] Direction of air flow is towards ETO work area from non-ETO work areas.	Access to ETO work area is restricted to authorized[j] personnel. At end of cycle, operators enter chamber wearing protective equipment. Treated material aerated in chamber room for minimum of 24 hours. Protective equipment worn by operators include 3M hardcap tether which is designed to provide Grade D breathing air[g] (air compressor source, carbon monoxide monitor, filter, oil filter, and compressor high temperature shut down) and gloves. ETO workers follow written procedures on sterilization process. Preventative maintenance is performed on all sterilizer equipment, including air compressors and breathing apparatus. Monitoring equipment is calibrated.	Monitoring is being conducted with Wilks-Miran and HNu equipment to determine aeration efficiency. Site reports that grab samples (charcoal) and TWA measurements have been performed. In response to monitoring data, ventilation has been increased, surveys have been conducted of air and water exhausts, and personal protective equipment utilized. Site reports that exposure has been reduced and that further tests are being conducted to determine total gain.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft³)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site Q	8.8	12% ETO 88% Freon®	Vented to atmosphere.	1-4	Not available.	Chamber equipped with dual vacuum and filtered air cycles for evacuation of gas. Aerator vented to outside atmosphere.	ETO work area measures 7'8" x 10'6" x 8'10". Area ventilation by HVAC unit. Rate of air exchange is 6 air changes per minute. Direction of air-flow is negative.	Access to ETO work area is limited to 1-4 ETO operators, Quality Control labeling technicians and micro-lab personnel. At end of cycle, chamber door is opened 3 inches, the room is evacuated and locked for 3 minutes. At the end of this period the operators re-enter the room, unload the baskets containing treated materials and place them side-by-side on a table-top for 30 minutes. Loose pouches are transferred to small baskets and placed into an aeration cabinet. Workers do not enter either sterilizer or aerator. The room is opened and post-sterilization inspection continues. Operators wear head covers, lab coats, and captive shoes. Each sterilizer operator undergoes thorough training program based upon HIMA suggested guidelines modified to fit company's special aspects. Program requires approximately 2 weeks of full time involvement. At the end of	Monitoring has been conducted. Levels of ETO were found to be acceptable. Additional data not available.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site Q (Concluded)								program, a test is given to operator to document his proficiency. Regular schedule of equipment inspection and maintenance including monthly mechanical/electrical preventive maintenance checks, quarterly calibration of all instruments (in compliance with GMP), and semi-annual monitoring for ETO levels.	

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{b}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{b}
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{b,c}	Work Practices^{b}	
Site R	3(900) 1000	12% ETO 88% Freon®	All chambers vented to outside atmosphere	9	Access to ETO work area is not restricted to ETO operators.	(4) Continuous purge system. (4) Compressed air flush. (1) High volume blower flush.	The ETO work area for each set of sterilizers is located in a general work area that is part of a warehouse. In each warehouse there is mechanical area ventilation. The volume and rate of air movement for each warehouse for each set of sterilizers (as represented by groupings in column 2) are 1.23 million ft^3 (180' x 256' x 30') and 20,000 cfm^{d} (provided by 6 units), 2.4 million ft^3 and 8700 cfm^{d} (provided by 8 units units), and 0.23 million ft^3 and 4300 cfm^{d} (provided by 2 units), respectively.	ETO operators fully responsible for ETO sterilization work which includes moving materials in and out of area, loading and unloading sterilizers, and monitoring cycles as they progress. At end of cycle, chamber door is opened approximately 6 inches. Then there is a 1 hour time delay before operator can enter chamber. Worker uses electric forklift truck to remove treated materials from chamber. Operators are required to wear goggles and charcoal-filtered masks when unloading sterilizers and to wear gloves (in addition to goggles and masks) when changing gas cylinders. Workers are trained by operations personnel according to existing protocols as to their responsibilities. Yearly maintenance schedule is set up for all hardware, pumps, blowers and filters and quarterly calibration inspection done to controls.	Monitoring was performed using Century Systems Corporation model OVA-118. Additional data not available.
	900	12% ETO 88% Freon®				(2) Continuous purge system.			
	900	10% ETO 90% CO_2				(1) Compressed air flush.			
	1150	12% ETO 88% Freon®				(1) High volume blower flush. (1) Continuous purge system.			

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site 8[h]		12% ETO 88% Freon® in all sterilizers		>16	Not available.		Mechanical area ventilation in all ETO work area.	Access to sterilization and aeration areas limited to authorized personnel. At completion of the sterilization cycle, sterilizers equipped with vacuum capabilities draw an additional vacuum. The door is then opened approximately one inch and air is drawn into sterilizer by the vacuum pump system. Local exhaust ventilation is used at the lower edge of the sterilizer door on the open side. Doors remain in this position for 30 minutes before product is removed. For larger palletized product, sterilizers equipped with rear vent exhaust through the sterilizer for 30 minutes before the door is fully opened and the product is removed. Exhaust through the rear vent remains on throughout the unloading process. For sterilizers equipped with rear vent exhaust systems (to draw air through the sterilizer away from the operator) pallets are removed using a	General air samples and personnel samples have been monitored at all 4 locations using the Qazi-Ketcham charcoal tube method and Wilks-Miran-101 instruments. In response to data obtained from such monitoring, various changes have been made with both the equipment and procedures which have reduced ETO levels both in the sterilizer areas and in the general work area. Changes in equipment include longer aeration following sterilization cycles and installation of rear vent exhaust systems to exhaust sterilizers directly to the atmosphere during the unloading. Hoods have been installed over sterilizer doors where this type of installation provided adequate control of ETO emissions. Isolated areas for
Location 1	1.68		Vented to atmosphere.			Canopy hood located above sterilizer.	Sterilization conducted in work area (76'6" x 29' x 9'6"); 10 air changes per hour.		
	2615 2343		Both vented to atmosphere.			Rupture disc in ETO supply line venting to exhaust duct if pressure problem appears; chamber doors are well-gasketed.	Sterilization conducted in 40' x 27' x 12' back room. Normal exchange with ceiling diffusers. 8-hour exhaust through chambers when venting.		
	24		Vented to atmosphere.			Multiple air flushes at end of sterilization cycle.	Sterilization conducted in 24' x 11' x 12' room.		
	144		Vented to sewer drain.			Sterilizer is double ended and opens into two rooms; water-sealed vacuum pump evacuates	Sterilization rooms are 32' x 16' x 12' and 40' x 23' x 12'.		

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site 5[b] Location 1 (Continued)						chamber 3 times at end of cycle; canopy hood located over each door.		hand-operated pallet truck. Entry into sterilizers not equipped with a rear vent system is not permitted. The pallets are pulled on rollers to the sterilizer door and then removed by either a fork lift truck or a hand-operated pallet truck. To enter these sterilizers (either to remove pallets or spilled material) sterilizer operators must wear either air-supplied respiratory protection or self-contained breathing protection. Freshly sterilized products are removed to isolated areas, such as warehouse or storage space, where they aerate for at least 24 hours. Personnel are not permitted in these areas during this period—except for placement of freshly sterilized product or removal of finished product. Exhaust fans in the ceiling and in the side walls are used to remove ETO vapors directly to the outside atmosphere. Workers wear protective gloves, splash-proof chemical goggles, or full face shield	aeration of product following sterilization have also been set up where necessary. Work procedures and practices have been modified to reduce exposures to the lowest possible level. Personnel exposed to ETO are trained in these procedures and in emergency procedures. Procedures and practices are modified when industrial hygiene information indicates ETO exposures are higher than desirable. Industrial hygiene surveys are performed periodically using both personnel samples and general area measurements to confirm that procedures and equipment are operating satisfactorily and to evaluate changes in procedures and equipment. Lower 8-hour Time Weighted Average readings were obtained at two different locations after changes
	90 148.3		Both vented to atmosphere.			Both sterilizers manufactured by AMSCO. Large chamber is double-ended.	Sterilization rooms measure 20' x 13'6" x 10' for small chamber and 22' x 14' x 9' and 33' x 8'6" x 9' for large chamber. ETO cylinders and controls located in separate machine room (which has an ETO alarm). Exhaust fan located above cylinders.		
	289		Vented to atmosphere.			Vacuum pump to drain.	Sterilization room measures 63' x 18' x 10'; 20 air changes per hour; ETO tanks located in separate room.		

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{b}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{b}
	Size of Sterilizer (ft^{3})	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{b,c}	Work Practices^{b}	
Site 8^{h} (Continued) Location 2	65		Vented to atmosphere (gas) and to drain (condensate).			Double-ended; Liquid/gas separator; multiple post-vacuums.	Preparation Room (load side of sterilizer) is 42' x 12' x 9' with air movement rate of 2500 cfm; air exhausted through ceiling vents directly above sterilizer doors. Corridor at discharge side of sterilizer is 36' x 8' x 9' with air movement rate of 1600 cfm;^{d} air exhausted at floor level.	during hook-up and break-down of ETO lines to cylinders and storage tanks. Respirators are required whenever entry into a sterilizer containing ETO is required or during an emergency if a leak should occur. Personnel working with ethylene oxide sterilization processing are trained in the hazards of ETO and ETO/freon® mixtures, the symptoms that may occur from an exposure or overexposure; normal operating procedures for the sterilizers which they operate, procedures which reduce the potential for exposure to ETO to a minimum, and training in emergency procedures.	(unspecified) were made in operating procedures and equipment.^{i} Gas Tech monitor model 1565, with 4 pick-up points (load side, unload side, sterilizer service area, and ETO tank manifold), dual alarm levels (20 ppm and 30 ppm), and audio-visual alarms are to be installed in area around 65 ft^{3} sterilizer.
Location 3	(6)1000		Vented to drain.				Sterilization room is 104' x 31' x 20'. Rear exhaust vent and low level vent at bottom front corner of one chamber, and low level vent at bottom front of another chamber. Both added by facility.	Inspection and maintenance requirements vary at this firm's four locations. Contract maintenance and inspection services are utilized at some locations, while at larger locations in-house maintenance personnel perform periodic inspections of the sterilizers and the operating equipment.	

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{b}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{b}
	Size of Sterilizer (ft^{3})	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{b,c}	Work Practices^{b}	
Site E^{h} (Continued) Location 4	(4)850 (4)1000		Vented to atmosphere.				(4) 850 ft^{3} sterilizers located in 2 rooms (25' x 29' x 21' each). (4) 1000 ft^{3} sterilizers located in 50' x 90' x 115' room. Exhaust ventilation fan and duct in top of 1000 ft^{3} sterilizer rated 1800 cfm.^{d} Mechanical area ventilation of ETO cylinder manifold room.		

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site T	1953	12% ETO 88% Freon®	Vented to roof-top vent to atmosphere.	1-4	Access ETO sterilization area is not limited to ETO sterilizer operators; sterilizer and test area located adjacent to access way used by other personnel. Operators must enter chamber to unload treated materials. Operators must open cases containing treated materials to remove biological indicators and then reseal case almost immediately after treated materials are removed from the chamber.	No less than 2 vacuum/air exchanges at end of cycle. Chamber equipped with liquid ring vacuum pump for evacuation. Service water pumped to open floor drain.	Sterilization conducted in open, L-shaped warehouse that measures 10,000' on long leg and 5,000' on short leg, with sterilizer located at their juncture (total warehouse measures approximately 90,000 ft^2). Passive area ventilation. Facility reports rate of air exchange is nominal and that there is free movement of air.	At end of cycle, operator opens door, then leaves area for not less than 5 minutes. Upon return, he monitors ETO concentration at open doorway with Wilks-Miran 101 specific vapor analyzer to determine if ETO concentration is no more than 30 ppm (typical values range from 10 to 40 ppm). Operator then enters chamber to move pallets to doorway, which are then retrieved by forklift and transferred to open "on-test" area 20' from sterilizer. Operators receive supervisory instruction and detailed written procedures. Sterilizer is inspected and lubricated weekly and monthly; overhaul of pumps and fans performed quarterly and semi-annually.	Refer to Work Practices column.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{b}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{b}
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{b,c}	Work Practices^{b}	
Site U	1700	12% ETO 88% Freon®	Gas exhausted by pulsing vacuum to outside atmosphere.	5-8	Access to sterilizer and quarantine area is not restricted to sterilizer operators. Operators must enter chamber to unload treated materials.	Chamber equipped with two air washes.	Sterilization conducted in general work area measuring 1,500,000 ft^3. Mechanical area ventilation (fans) with air exchange ranging from 0 to 24,000 cfm^{d} depending on outside environment. Quarantine area measures 840 ft^2 (within 100,000 ft^2 warehouse).	Door seals are loosened during second air wash vacuum. As second air in-bleed occurs, operator opens both chamber doors. There is usually a 5 minute delay between the opening of the sterilizer door and retrieval of the treated materials. Operators transfer individual pallets (containing ETO-treated material) with fork-lift from chamber to quarantine area for approximately 14 days. Operators trained in sterilization procedures, safety, and ETO handling. Preventative maintenance is performed on major equipment, such as pumps. Vessel and monitoring equipment are calibrated monthly.	Monitoring is performed using gas chromatograph. Additional data were not reported.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{b}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{b}
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{b,c}	Work Practices^{b}	
Site V	384	12% ETO 88% Freon®	Vented to atmosphere.	1-4	None	Chamber equipped with two air washes and two post-vacuums. Chamber equipped with exhaust system that operates while chamber door open is after completion of sterilization cycle.	Sterilization conducted in Hospital Disposables Manufacturing Area, which measures 30' x 16' x 10'. Two ventilation systems used: (1) heating/ventilating roof-mounted air handler which provides a rate of air exchange of 34.25 air changes per hour and (2) slotted pick-up at bottom of door and at floor drain ventilation (grille) which provides a rate of air exchange of 1400 cfm.^{d} The direction of air flow is down from the ceiling to the floor with both systems.	Access to ETO sterilization area is restricted to authorized personnel. Following air washes and vacuums at end of cycle, sterilizer door is opened approximately 16 hours before treated materials are retrieved. Operator transfers treated product with hand-lift from sterilizer to quarantine area in warehouse. Operator wears protective clothing (chemical goggles, respirator, full face shield, gloves, and protective suit) when changing ETO tanks or when monitoring system indicates a gas leak in the sterilizer area. Operator training in ETO procedures includes facility's written standard operating procedures and on-the-job training. Maintenance department inspects each section of the sterilizer on a periodic basis.	Tank storage area and sterilizer room are continuously monitored with Miran-101-ETO Vapor Analyzer, (2) Enmet ETO Gas Monitors, and Foxboro Gas Chromatograph. On March 24, 1980, North Carolina Department of Human Resources, Occupational Health Branch, conducted ETO survey of sterilizer area and of employees involved with sterilization. Survey indicated that there was no hazardous exposure to operators while unloading sterilizer. No detectable amounts of ETO were found in samples taken and only "trace" amounts of Freon-12 were found during venting and vacuum portions of sterilization cycle. On July 17, 1980, four employees that were directly and indirectly in contact

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft³)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site V (Continued)									with the sterilizer area were tested for chromosomal abnormalities. Results were well within "normal limits". Facility reports that these tests will form a baseline for monitoring its employees with potential exposure to ethylene oxide. In response to data obtained from monitoring, the following changes were made: the sterilizer operator's desk was removed from the sterilizer room to decrease significantly exposed time to the sterilizer; exit areas and evacuation routes have been established in case of an emergency; a "closet-like" area was built for the tanks in use; new gas lines have been installed; gas vendors were changed for higher quality of gas and cylinders used in the tanks; and checks of

TABLE C-3 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of EtO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site V (Concluded)									the entire sterilizer operation are being conducted by the maintenance department on a periodic basis for gas leaks.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site W	86	12% ETO 88% Freon®	Vented to outside atmosphere.	1-4	Access to ETO sterilization area is not restricted; however, warning signs are posted in sterilization area (Facility reports that area is soon to be separated from other work areas to reinforce access restrictions.) Treated materials are transferred manually from sterilizer area to staging area. Treated material is not formally aerated.	Sterilizer manufactured by AMSCO. Chamber equipped to draw three air purges. Chamber equipped with diaphragm locking mechanism which locks door when chamber is in operation.	Sterilization area is open to other areas from the top (no ceiling), is located in a common area with shipping and receiving departments, and measures 40' x 16'. Mechanical area ventilation (ducting) with one air change every 72 minutes (approximately). Direction of airflow is positive (from sterilizer area to outside).	At the end of the cycle, the operator opens the sterilizer door 6 inches, then leaves the area for at least 15 minutes before removing treated material from the chamber. Treated material is pulled out of sterilizer on a "rollout" cart; therefore operator does not have to enter chamber. Operators wear lab coat and latex gloves when changing ETO tanks and when processing material (either before or after decontamination). Operators receive on-the-job training. Facility contracts with AMSCO for bimonthly preventive maintenance. This includes cycling of machine, checking valves, changing filters, inspecting door seals, and other measures.	Monitoring of environmental levels has been performed using Wilks-Miran 1-A infrared spectrophotometer, gas chromatography, and Draeger indicator tubes. Additional data were not reported.

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site X	770 880 (3)1650	100% ETO	Vented to atmosphere and to sewer.	9-12	Operators must enter chamber to unload treated materials.	Two post-vacuums.	Sterilization conducted in separate room which measures 3,026 ft^3. Mechanical area ventilation with 4 air changes per hour. Direction of airflow is towards ETO work area from non-ETO areas. Half of the aeration area is vented to the outside atmosphere, while in the other half the air is recirculated.	Access to ETO work area is limited to authorized personnel. 10 minutes before end of sterilization cycle door hinges are loosened. At end of cycle, chamber door opened for 15 minutes before treated materials are removed from the chamber. Treated materials are removed from chamber with a forklift. High residual products moved to aeration room and low residual products moved to warehouse quarantine racks. Facility reports that operators receive "regular" testing and schooling in ETO sterilization procedures. Preventive maintenance conducted daily and documented. Hourly investigations and documentation of process control equipment. Corporate calibration program provided on scheduled basis for process control equipment.	None (as of 8/80). Facility intends to purchase Wilks-Miran 101 for routine monitoring (by 9/80).

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[b]	
Site Y	367 1300 1700	12% ETO 88% Freon®	Vented to atmosphere.	3-8	None	Three air washes are performed.	Sterilization conducted in building (84' x 36' x 20') vented by roof blower and side fan. Direction of air flow is towards the ceiling and from the side. Warehouse used for aeration is vented at its ceiling with (10) 18" diameter natural draft ventilators. Floor area is vented by power fan which supplies air at a rate of 6,000 cfm.[d] Two supply fans within swamp coolers in ceiling area (together) supply air at a rate of 4,000 cfm.[d]	Access to ETO sterilization area is restricted to authorized personnel. At the end of the third air wash, sterilizer doors are opened approximately 6 inches for 3 minutes (while floor level wall exhaust fans operate). After 3 minutes, operator returns to open doors wide; then after another 3 minutes, the treated materials are removed from the chamber. A pole and hood are used to pull the skids out of the sterilizer and a forklift is used to move the skids to a warehouse for aeration. Operators wear goggles when changing ETO cylinders. Operator training is conducted by Sterilization Lead Operator and Sterilization Supervisor, and evaluated by Sterilization supervisor. ETO sterilization equipment is inspected weekly. Maintenance is performed only upon equipment malfunction.	Monitoring is conducted periodically by Corporate Safety Engineer. Type of equipment used and results obtained were not reported; however, in response to data obtained from monitoring one change has been made in operating procedures (a time delay of 15 minutes between opening of chamber door and unloading of treated materials).

TABLE C-2 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design[b,c]	Workplace Design[c]	Work Practices[b]	
Site Z		12% ETO 88% Freon® in all sterilizers				Chambers are equipped with door interlocks (6), local exhaust ventilation (6), one post-vacuum (4), 30 minute air wash after completion of cycle (4), and automatic door opening (1). In addition, ETO tank storage areas vented (6), check valves in ETO gas lines (5), and air displacement bleed outside (2). Aeration chambers vented to outside atmosphere.	Mechanical area ventilation in all ETO work areas.	Access to all ETO work areas is restricted to authorized personnel. At completion of the sterilization cycle, the sterilizer door is opened for 10-15 minutes before treated materials are unloaded (4); the sterilizer door is opened and the operator leaves the sterilizer room for a minimum of 15 minutes; the sterilizer door is opened automatically and the operator leaves the sterilizer room for a minimum of 15 minutes (1). Operators do not enter chamber to remove treated materials. Operators wear gloves while transferring treated materials from sterilizer to aerator; respirators are available to operators at three ETO work areas in the event of major spills or leaks; and a face shield is worn when changing ETO tanks in two ETO work areas. All sterilizer operators are required to attend operator certification classes. There is a regularly scheduled program of equipment inspection and maintenance.	ETO work areas monitored with Wilks-Miran 1A gas analyzer. Levels were found to exceed 100-200 ppm when the chamber door was opened and while changing tanks (gas line bleeding). In response to these data, local exhaust vents were installed over the chamber door, at the drain, and over the tanks. Monitoring performed subsequent to this installation detected ETO levels below 5 ppm (8 hour time weighted average). Facility also reported that peaks rarely reach 15 ppm.
	4.5		Vented to sewer drain.	1-4			Sterilization conducted in separate room (6' x 10' x 8').		
	6.75		Vented to outside atmosphere.	1-4			Sterilization conducted in general work area (8' x 15' x 9').		
	9.3		Vented to sewer drain.	1-4			Sterilization conducted Microbiology Lab (26' x 35' x 12').		
	25		Vented to sewer drain.	1-4			Sterilization conducted in production area (60' x 90' x 8').		
	30		Vented to sewer drain.	1-4			Sterilization conducted in separate room (13' x 22' x 9').		
	70.9		Vented to outside atmosphere.	1-4			Sterilization conducted in separate room (19' x 16' x 12').		

TABLE C-2 (CONCLUDED)

[a] Indicates a range of the total number of persons authorized to operate ETO sterilization equipment at this facility, unless otherwise indicated.

[b] Data in this column apply to all ETO sterilizers, ETO work areas, or ETO sterilizer operators at this facility, unless otherwise indicated.

[c] Where indicated, the dimensions of ETO work areas or ventilation/aeration areas represent length x width x height.

[d] This represents cubic feet per minute (cfm).

[e] This represents pounds per square inch gauge. A gauge pressure is the difference between a given pressure and that of the atmosphere (Per[illegible] 1950).

[f] Tethered personnel refers to those personnel wearing air-line respirators. Air-line respirators consist of a facepiece or head-covering helmet or hood to which air is supplied from a source of compressed air (Sax 1979).

[g] Grade D breathing air is an OSHA requirement for air quality and is described in Commodity Specification G-7.1-1966 of the Compressed Gas Association.

[h] To present an orderly sequence of the operating procedures followed at this medical products firm, and due to the general nature of some of the data reported by this firm, complete data on work practices and partial data on equipment design are presented under the Work Practices column.

[i] The results of these changes for the two locations are:

Bulk Product Sterilization	Before (8 Hr. TWA)	After (8 Hr. TWA)
A. Sterilizer Operators	25	2.2
Quality Control Personnel	23	1.6
Packaging Personnel	29	2.4
B. Sterilizer Operators	12	8

TABLE C-3

PRACTICES RELATIVE TO WORKER EXPOSURE AT SELECTED LIBRARY SITES

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Chicago Historical Society Chicago, IL.	Vacudyne/ 18/3	12% ETO 88% Freon®	Exhausted via hose through a window pane to the outside atmosphere.	One at a time but total number unknown.	No regular inspection or maintenance program which may result in undetected leakage. Fumigation conducted in unrestricted area. Limited air ventilation and circulation in area. Treated material left in closed chamber for 1-24 hours after conclusion of cycle.[d] No time delay between opening of door and unloading the chamber. Aerated in storage area. No operator training program. No protective gear worn while operating chamber.	One post-vacuum.	None	None	None

SOURCE: Brubaker, 1978; 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Harvard University Cambridge, MA.	Vacudyne/ 18/2	12% ETO 88% Freon®	Exhausted via a pipe to outside atmosphere.	2	No regular inspection and maintenance program which may result in undetected leakage. Treated material left in closed chamber 1 to 48 hours after completion of cycle.[d] No time delay between opening the door and unloading the chamber. No aeration facility; treated material shelved or sent to Preservation Section. No protective clothing worn while operating chamber.	One post-vacuum.	Fumigation conducted in restricted area.	In-house operator training.	None

SOURCE: Freitag, 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Herbert Hoover Institute Stanford, CA.	Vacudyne/ 100/2	12% ETO 88% Freon®	Exhausted via pipe to outside atmosphere.	1	No regular inspection and maintenance program which may result in undetected leakage. Limited room ventilation. Aerated in storage area. No protective gear worn while operating chamber.	Two successive post-vacuums.	Fumigation conducted in restricted area.	Operator trained by manufacturer. Occasional checks for leakage by the Stanford University Health Officer. Time delay between opening of door and unloading of chamber.	None

SOURCE: Fair, 1978; 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Library of Congress Washington, D.C.	Devine/ 420/22	10% ETO 90% CO_2	Exhausted via a metal pipe to outside atmosphere.	Two at a time, total of four.	No aeration facility; treated materials left in hallway until shelved.	Two to three successive post-vacuums.	Air exchange every 30 minutes. Fresh air inlet above chamber, exhaust system behind chamber and on the wall to the left of chamber. Fumigation conducted in restricted area.	Periodic in-house inspection. Soap solution used for leak testing. Time delay of 1 to 24 hours between first opening of door and unloading of treated items. In-house operator training. Gloves and coats worn while operating chamber.	Most recent monitoring was about 4 years ago. Charcoal tube used to monitor ETO levels in the air. Very low levels (0.5 ppm) detected.

SOURCE: McComb, 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Maine State Archives Augusta, ME.	Vacudyne/ 90/10	10% ETO 90% CO_2	Spent gas passed through a water wash before exhausted to outside atmosphere.	2	No regular inspection and maintenance program may result in undetected leakage. No ventilation in chamber room. Fumigation conducted in unrestricted area. No protective gear worn while operating the chamber. No aeration facility.	Two to three successive post-vacuums.	None	Operator trained by manufacturer. Chamber room equipped with emergency breathing gear. Time delay of 6-24 hours between opening of door and unloading chamber.	None

SOURCE: Clark, 1978; 1979; 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Massachusetts Historical Society Boston, MA.	Vacudyne/ 18/8	12% ETO 88% Freon®	Exhausted to outside atmosphere.	2	Fumigation conducted in unrestricted area. Time delay of 24 hours between opening of door and unloading of chamber. Operator work stations located in same room as sterilizer. No protective clothing worn while operating the chamber. No aeration facility. No operator training program.	One post-vacuum.	Area is air-conditioned. Fume hood installed 2' above the chamber door. A fan installed across from chamber.	Equipment serviced once per year. Gasket replaced twice a year.	None

SOURCE: Bentley, 1978; 1979; 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
National Archives Washington, D.C.	Guardite/ 380/43	10% ETO 90% CO_2	Exhausted via metal pipe to outside atmosphere.	1	Fumigation conducted in unrestricted area. No ventilation in fumigation room. No regular inspection and maintenance program may result in undetected leakages. Treated material left in closed chambers for several hours after completion of cycle.[d] No time delay between opening of door and unloading the chamber. No protective clothing worn while operating chamber. No aeration facility.	One post-vacuum.	Area equipped with sprinklers in case of fire.	One floor fan installed for use in the summer months. In-house operator training.	None

SOURCE: Gear, 1978; 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
New England Document Conservation Center Andover, MA.	Vacudyne/ 100/5	12% ETO 88% Freon®	Exhausted via pipe to outside atmosphere.	1	No regular inspection and maintenance program which may result in undetectable. leakage. No protective clothing worn while operating chamber. No time delay between opening of door and unloading the chamber. No aeration facility.	Gas post-vacuum.	Custom designed truck mounted chamber. Three large doors opened during the operation of chamber.	In-house operator training program.	None

SOURCE: Ogden, 1979; 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
North Carolina Archives and Record Section Raleigh, NC.	Vacudyne/ 300/11	10% ETO 90% CO_2	Exhausted to outside atmosphere.	2	Fumigation conducted in unrestricted area. No regular inspection and maintenance program which may result in undetectable leakage. Limited chamber room ventilation. No protective clothing worn while operating chamber. Treated material aerated in storage area.	Equipment fitted with an internal exhaust system which is operated for 12 hours after conclusion of cycle. One post-vacuum.	None	Operators trained by manufacturer. Time delay of several hours between opening of door and unloading of chamber.	None

SOURCE: Hoffman, 1978; 1979; 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Pennsylvania State Archives Harrisburg, PA.	Vacudyne/ 270/13	12% ETO 88% Freon®	Exhausted to outside atmosphere.	3	No regular inspection and maintenance program which may result in undetectable leakage. Limited chamber room ventilation. Fumigation conducted in unrestricted area. No protective clothing worn while operating chamber. Treated material aerated in storage area.	Three successive post-vacuums.	None	Time delay of several hours between opening of door and unloading the chamber. Operators initially trained by chamber manufacturer. State approved breathing apparatus readily available in case of emergencies.	None

SOURCE: Shelley, 1978; 1979; 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Pennsylvania State University Pattee Library University Park, Pa.	Vacudyne/ 18/6	12% ETO 88% Freon®	Exhausted via pipe to outside atmosphere.	One at a time. Total number unknown.	No regular inspection and maintenance program may result in undetectable leakage. Limited chamber room ventilation. Fumigation conducted in unrestricted area. Treated material left in closed chamber for several hours after completion of cycle.[d] No time delay between opening of door and unloading chamber. No aeration facility. No protective gear worn while operating chamber. No operator training program.	One post-vacuum.	None	None	None

SOURCE: Fellipelli, 1980.

TABLE C-3 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Wisconsin State Historical Society Madison, WI.	Vacudyne/ 300/10	12% ETO 88% Freon®	Exhausted to outside atmosphere.	1	No regular inspection and maintenance program may result in undetectable leakage. Limited chamber room ventilation. Treated material left in closed chamber for several hours after completion of cycle.[d] No time delay between opening of door and unloading the chamber. Treated material aerated in storage area. No protective gear worn while operating chamber.	One post-vacuum.	Fumigation conducted in restricted area.	Operator trained by chamber manufacturer.	None

SOURCE: Mohler, 1980.

TABLE C-3 (CONCLUDED)

[a] Fumigation cycle operated at negative pressure unless otherwise noted.

[b] Refers to the total number of persons authorized to operate ETO fumigation equipment.

[c] Fumigation and air-wash cycles manually operated unless otherwise noted.

[d] Continued offgassing during this period may result in elevated ETO concentrations in the chamber. Operators unloading the chamber may be exposed to these concentrations.

TABLE C-4

PRACTICES RELATIVE TO WORKER EXPOSURE AT
SELECTED MUSEUM SITES

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Lincoln Memorial University Harrogate, TN.	Vacudyne/ 64/3	12% ETO 88% Freon[c]	Exhausted via duct to atmosphere.	1	No regular inspection or maintenance program which may result in undetected leakage. Fumigation conducted in unrestricted area. Limited room ventilation. Treated material left in closed chamber up to 48 hours after conclusion of cycle.[d] No time delay between first opening of door and unloading of treated material. Chamber unloaded manually. No aeration of treated material.	A "back-flow meter" fitted into gas vent hose to monitor any backups during exhaust process. One post-vacuum.	None	Protective mask, gloves and lab coat worn while operating chamber. In-house training program. Occasional test for leakage by (1) checking gas gauge at beginning and end of cycle for loss of pressure and (2) using soap solution around seals and fittings.	None

SOURCE: Archer, 1978; 1979; 1980.

TABLE C-4 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Lowie Museum of Anthropology Berkeley, CA.	Vacudyne/ 486/4	12% ETO 88% Freon[c]	Exhausted via water-sealed vacuum pump to sewer.	3	No protection gear worn while operating chamber. Chamber unloaded manually. No aeration of treated material.	Up to 3 successive vacuums may be drawn at the conclusion of the cycle.	Chamber mounted in a 21' standard highway semi-trailer vehicle. Trailer equipped with 4 vents and a fan.	Routine in-house inspection of equipment. Equipment checked periodically by pest control officer. Halide detectors used to detect leakage.[e] Time delay of 1-4 hours between first opening of door and removal of treated material. In-house training program. Fumigation equipment and procedures periodically checked by University Environmental Safety and Health Dept.	Monitored when equipment initially installed. Monitoring equipment available from California OSHA Dept.

SOURCE: Brown, 1979; 1980.

TABLE C-4 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment^a			Total Number of Operators^b	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Museum of History and Technology Washington, D.C.	AMSCO^f/ 30/5	12% ETO 88% Freon	Exhausted via a "condenser" where spent gas is mixed with running tap water, which is then conducted to sewer drain.	3-4	No aeration of treated material.	Equipment modified to automatically draw up to 5 successive post-vacuums.	Fumigation conducted in restricted area. Alarm on chamber room door which alerts guards whenever it is opened. Guards warned by telephone when authorized entrance is to be made. Illuminated safe/ unsafe warning signs placed above entrance door activated by a switch in duct detecting airflow. Chamber room ventilated with unconditioned air at the rate of 30 changes per hour. Room vented at floor level near the point where gas mixture emerges to the air, at mid-height, and near the ceiling. Room air exhausted to the atmosphere.	Equipment serviced by manufacturer semi-annually. "Halide detectors" used around seals and gaskets to monitor for leakage.^{e} Gauges monitored for any drop in pressure during fumigation cycle. Protective gas mask worn while operating chamber. Polypropylene gloves worn when handling gas cylinders. Material loaded in a cart which is wheeled into chamber. Time delay of 30 minutes between first opening of door and removal of treated material. In-house operator training program. Initial training by the manufacturer.	Monitoring conducted in 1978 using Wilks-Miran IR gas analyzer. ETO concentration recorded in excess of 130 ppm upon door opening. Equipment and procedures modified as a result of the monitoring data. No follow-up studies have been conducted.

SOURCE: Calahan, 1979; 1980; Organ, 1979, 1980.

TABLE C-4 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Museum of Natural History Washington, D.C.	AMSCO[f]/ 100/21	10% ETO 90% CO_2	Exhausted via pipe to atmosphere.	1	No regular inspection or maintenance program which may result in undetected leakage. Restricted access but potential passive exposure to employees in loading area adjoining chamber room due to a window size opening near chamber room door. Limited room ventilation. No protective gear worn while operating chamber. No operator training program.	One post-vacuum.	None	Time delay of several hours between first opening of door and removal of treated material. Treated material transferred from chamber room to other area with 8 to 10 air changes per hour.	None

SOURCE: Pierce, 1980; Russell, 1980.

TABLE C-4 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Museum of Our National Heritage Lexington, MA.	Vacudyne/ 24/4	12% ETO 88% Freon®	Exhausted to atmosphere.	4	No regular inspection or maintenance program which may result in undetected leakage. Fumigation conducted in unrestricted area. Limited room ventilation. Treated material left in closed chamber for several hours after conclusion of cycle.[d] No time delay between first opening of door and unloading of treated materials. No protective gear worn while operating chamber.	One post-vacuum.	None	Operators trained by manufacturer.	None

SOURCE: Osborne, 1979; 1980.

TABLE C-4 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Old Sturbridge Village Sturbridge, MA.	Kewaunee/ 192/11	12% ETO 88% Freon®	Exhausted to atmosphere.	3-4	No regular inspection or maintenance program which may result in undetected leakage. Fumigation conducted in unrestricted area. Limited room ventilation. Chamber unloaded manually. No time delay between first opening of door and removal of material. No aeration of treated material. No operator training program.	Three hour air-wash cycle run at end of fumigation cycle.	Exhaust fans installed in chamber room for use in the summer months.	None	None

SOURCE: Curtis, 1979; 1980.

TABLE C-4 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft³)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Winterthur Museum Winterthur, DE.	Unknown/ 640/11	12% ETO 88% Freon®	Exhausted to atmosphere.	1	Limited room ventilation. No protective gear worn while operating chamber. Chamber unloaded manually depending on the type of material being treated. No time delay between first opening of door and removal of material. No aeration of treated material.	Twenty-four hour air-wash cycle performed at end of fumigation cycle.	Fumigation conducted in restricted area.	Equipment serviced twice a year. Operator certified by the State of Delaware.	Leakage tested via gas chromatography. Additional data not available.

SOURCE: Reilly, 1979; 1980.

TABLE C-4 (CONCLUDED)

[a] Fumigation cycle operated at negative pressure unless otherwise noted.

[b] Refers to the total number of persons authorized to operate fumigation equipment.

[c] Fumigation and air-wash cycles manually operated unless otherwise noted.

[d] Continued offgassing during this period may result in elevated ETO concentrations in the chamber. Operators unloading the chamber may be exposed to these concentrations.

[e] Halide detectors detect the presence of Freon® by a change in the flame color.

[f] Fumigation cycle operated at positive pressure.

TABLE C-5

PRACTICES RELATIVE TO WORKER EXPOSURE AT
SELECTED RESEARCH LABORATORIES

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Charles River Associates Wilmington, MA.	(1) Consolidated/ 30/4-23 (2) AMSCO/ 80/4-23 (3) Hodges/ 225/4-23	20% ETO 80% CO_2	Spent gas.	16	Limited ventilation in sterilization area. Treated material left in closed chamber for several hours after completion of cycle.[d] No time delay between opening of door and unloading chamber. Treated material aerated in a holding area.	Two successive post-vacuums.	Chambers placed between a sterile and non-sterile area. Exhaust system has been installed near the chambers.	Protective gear worn while operating chamber in sterile area. In-house operator training program. Regular inspection and maintenance program. A Freon® detector is used to detect leaks around fittings and valves of the chambers.[e]	Continuous monitoring of sterilization area. Alarm is set off if ETO concentration levels exceed 50 ppm. Have not registered such levels yet.

SOURCE: Fitch, 1980; Slater, 1979.

TABLE C-5 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Frederick Cancer Research Center (Animal Production Facility) Frederick, MD.	(2) Castle/ 36/26	12% ETO 88% Freon®	Spent gas mixed with water and disposed of as ethylene glycol to sewer.	1	No protective gear worn while operating chamber. Treated material left in closed chamber for several hours after completion of cycle.[d] No time delay between opening of door and unloading of chamber. Treated material aerated in the chamber room.	Multiple post-vacuums.	Sterilization conducted in restricted area. Rate of air changes are 6-10 per hour in the chamber room area. Exhaust system has been installed near the chambers.	Eye goggles are worn while changing gas cylinders. Regular in-house inspection and maintenance program. A Freon® detector is used to detect leaks around fittings and valves of the chambers.[e] In-house operator training program. Sterilization procedures checked by the safety department.	Continuous monitoring of sterilization area with Wilks-Miran 101 specific vapor analyzer. Alarm is set off if ETO concentration levels exceed 50 ppm. Have not registered such levels yet. In 1979 monitoring was conducted using charcoal tubes. Samples of ambient air were taken while operator was operating chamber, unloading chamber and changing gas cylinders. Detected "very low" levels of ETO in air.

SOURCE: Davis, 1980.

TABLE C-5 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Frederick Cancer Research (Environmental Control and Research Lab) Frederick, MD.	(2) Castle/ 12/2-26 (3) AMSCO/ 20/2-26 (1) AMSCO/ 45/2-26	12% ETO 88% Freon®	Three units vented to the outside atmosphere and 3 to the sewer.	9	No protective clothing worn while operating chamber. No operator training program. No time delay between opening of door and unloading of chamber.	Three successive post-vacuums followed by a 30 minute air-wash cycle.	Sterilization conducted in restricted area. Rate of air changes is 6-10 per hour in the chamber room area.	Regular in-house inspection and maintenance program.	None

SOURCE: Hall, 1980; Hanel, 1979; 1980.

TABLE C-5 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
Jackson Laboratory Bar Harbour, ME.	Castle/ 30/7-18 Vernitron/ 4/7-18	12% ETO 88% Freon®	Exhausted to atmosphere.	2	Sterilization conducted in unrestricted area. No protective gear worn while operating chamber. Treated material left in closed chamber for several hours after completion of cycle.[d] No time delay between opening of door and unloading of chamber.	One post-vacuum.	Fumigation area ventilated and equipped with an exhaust fan.	Operator trained by manufacturer.	In 1979 monitoring was conducted using Draeger tubes. ETO concentrations between 20 to 30 ppm were detected at the breathing zone level after chamber door was opened at the end of the cycle.

SOURCE: Myers, 1979; 1980.

TABLE C-5 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
National Institutes of Health Allergics and Infectious Disease Bethesda, MD.	3M/ 2/3-4	100% ETO	Exhausted via copper tubing through the wall to the atmosphere.	3-10	Sterilization conducted in unrestricted area. Limited ventilation in sterilization area. No portective gear worn while operating chamber. Treated material left in closed chamber for several hours after completion of cycle.[d] No time delay between opening of door and unloading of chamber. No operator training program. Aerator vents into the workplace.	One post-vacuum.	None	None	None
	3M/ 2/3-4								

SOURCE: Janes, 1979; 1980.

TABLE C-5 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment[a]			Total Number of Operators[b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design[c]	Workplace Design	Work Practices	
National Institutes of Health, Veterinary Resources Branch Bethesda, MD.	Castle/ 200/2	12% ETO 88% Freon®	Spent gas mixed with water and disposed of as ethylene glycol to sewer.	1	Sterilization conducted in unrestricted area. Limited ventilation in sterilization area. Treated material left in closed chamber for a period of time after completion of cycle.[d] No regular inspection and maintenance program which may result in undetectable leakage. No operator training program. No protective gear worn while operating chamber.	One post-vacuum. Automatic door.	Treated material unloaded into "clean area" where the rate of air changes is 13 per hour.	Time delay between opening of door and unloading of chamber.	None

SOURCE: Bolte, 1980.

TABLE C-5 (CONCLUDED)

[a] Sterilization cycle operated at negative pressure unless otherwise noted.

[b] Refers to the total number of persons authorized to operate sterilization equipment.

[c] Sterilization and air-wash cycles manually operated unless otherwise noted.

[d] Continued offgassing during this period may result in elevated ETO concentrations in the chamber. Operators unloading the chamber may be exposed to these concentrations.

[e] Halide detectors detect the presence of Freon® by a change in the flame color.

TABLE C-4

PRACTICES RELATIVE TO WORKER EXPOSURE AT
SELECTED TRANSPORTATION SITES

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
AMTRAK Washington, D.C.	Not applicable.[a]	10% ETO 90% CO_2	Not applicable.	1	None	Not applicable.	Cars to be fumigated are moved to a separate track.	Fumigation procedures contracted to a professional extermination firm. Protective gear, i.e., gas mask, is worn by the operator. All openings except for exit door sealed with gum tape. Warning signs place around the car during the fumigation process. Car ventilated to open air at the completion of fumigation process.	Tester kits[b] employed to monitor interior of cars after aeration to determine ETO levels ("safe" levels must be obtained before cars returned to service).

[a] The procedure for fumigation of passenger cars entails release of ETO in the car and does not entail use of equipment such as a fumigation chamber.

[b] Gas Detector Kit, Model Number SG 4010 and Dectector Tubes, Model Number SG 4100-163 are manufactured by Liquid Industrial Gases, Chicago, Illinois.

SOURCE: McKenzie, 1979; Paluho, 1979.

TABLE C-7

PRACTICES RELATIVE TO WORKER EXPOSURE AT
SELECTED BEEKEEPING SITES

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Alabama[b,*]	Modified AMSCO Chamber/ 32/10	10% ETO 90% CO_2	Vented above chamber via 8 ft. long pipe.	4	Treated material hand carried.	Two successive post-vacuums.	Fumigation and aeration conducted outdoors.	Chamber door left open for 1 minutes before unloading. Regular maintenance program.	None
California[c**]	Minkoo/ 49/1	10% ETO 90% CO_2	Vented through a 50 ft. hose.	Not available.	None	Two successive post-vacuums.	Fumigation and aeration conducted outdoors.	Chamber door left open for 1 minutes before unloading. Rubber work gloves worn when handling material. Pallet used in loading and unloading chamber. Operators trained by California Dept. of Agriculture. Regular maintenance program.	Initially conducted by Calif. Dept. of Worker Health and Safety; no data available.

SOURCE: *Randall, 1980 and USDA, 1978; **Smith, 1980 and Vanderpool, 1980.

TABLE C-7 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Connecticut[b]*	Homemade/ 64/4	100% ETO (chamber i initially flushed with CO_2 t air)	Atmospheric chamber, no evacuation system. Vented by removing 4' x 4' chamber door.	1	Upon removal of door at conclusion of treatment period.	None	Fumigation and aeration conducted outdoors.	Chamber door left open 12 hours before half the load is removed; remainder remove after additional 12 hours. Regular maintenance program.	None
Delaware[b]**	Modified AMSCO Chamber/ 12/10	10% ETO 90% CO_2	Vented via pip through roof t atmosphere.	1	None	Four successive post-vacuums. Double door chamber with interior fan which operate after chamber doo opened to dissipate ETO.	Fumigation and aeration conducted in garage with restricted access Vent fan operate during fumigatio and aeration.	Chamber doors left open with fan operating for 20 minutes before unloading. Regular maintenance program.	None

SOURCE: *Farmer, 1980 and Newton, 1980; **Bowman, 1980.

TABLE C-7 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators^b	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Maryland^b*	Mishoo/ 49/4	10% ETO 90% CO_2	Vented via 40 ft. long hose	1	Chamber unloaded immediately after opening. Treated materials are hand-carried.	One post-vacuum.	Fumigation conducted outdoors; aeration conducted outdoors or in shed.	Regular cleaning and maintenance program.	None
Maryland^b** (Bioenvironmental Bee Laboratory)	AMSCO (hospital mattress disinfector)/ 86/13	12% ETO 88% Freon®	Vented to outside of greenhouse.	1	Treated materials occasionally are hand-carried.	One post-vacuum.	Fumigation conducted in greenhouse.	Chamber door generally left open for 24 hours before unloading; on occasion, cart is pulled out immediately. Regular cleaning and maintenance program.	None

SOURCE: *Vanden Bosche, 1980; **Knox, 1980; Shimanuki, 1980 and USDA, 1978.

TABLE C-7 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Mississippi[c,d]	Mixkon/ 49/4	10% ETO 90% CO_2	Vented through 50 ft. long hose.	3	Chamber unloaded immediately after opening chamber door. Treated materials hand-carried.	One post-vacuum.	Fumigation conducted outdoors; aeration conducted outdoors or in shed.	Treated materials not used for 24 hours after fumigation. Regular cleaning and maintenance program.	None
New Hampshire[c,d,e]	Mixkon/ 49/3	10% ETO 90% CO_2	Vented through 50 ft. long hose leading to outside of garage.	1	Treated materials hand-carried.	One post-vacuum. Vacuum pump operates for a 20 minute period after chamber door is opened.	Fumigation conducted in three-sided garage. Garage ventilated through hole in open wall.	Chamber door left open for 20 minutes before unloading. Use hooked pole to pull pallet out of chamber. Regular cleaning and maintenance program. Treated material aerated in garage for a minimum of 24 hours. Chamber operators are certified pesticide applicators.	None

SOURCE: [a]Fulton, 1980; [c-e]Keating, 1980 and USDA, 1978.

TABLE C-7 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators^{a}	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^{3})/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
New Jersey^{c}a	AMSCO (experimental model)/ 126/9	10% ETO 90% CO_2	Vented to roof of building.	3	Limited room ventilation. Treated material is aerated 15-20 ft. from chamber in warehouse. Treated material hand-carried.	One door of chamber located on inside of warehouse; the other door opens outside of warehouse. Two successive post-vacuums.	High-ceilings in warehouse.	In summer, both chamber doors are opened; in winter, only door in warehouse is opened. Chamber door left open for 30 minutes before unloading chamber. Regular cleaning and maintenance program.	None
New Jersey^{c}a	Mishoe/ 49/1	10% ETO 90% CO_2	Vented through dump valve immediately outside chamber.	Several, although only 1 operator per load.	Treated material hand-carried.	Two successive post-vacuums.	Fumigation conducted outdoors.	Chamber door left open for 30 minutes before unloading chamber. Regular cleaning and maintenance program.	None

SOURCE: ^{a}Matthewious, 1980.

TABLE C-7 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
New York[b]*	Homemade/ 30/5	12% ETO 88% Freon®	Vented through 1 ft. long pipe directly above chamber.	4	Treated materials hand-carried.	None	Fumigation conducted outdoors; aeration conducted outdoors or in shed.	Chamber door left open for 20 minutes before unloading. Hooked pole used to pull pallet out of chamber. Regular cleaning and maintenance program. Treated material aerated for a minimum of 6 hours.	None
North Carolina[c]**	Mickee/ 49/Not available	10% ETO 90% CO_2	Vented through a 50 ft. long hose.	1	Treated material hand-carried.	Two successive post-vacuums.	Fumigation conducted outdoors. Aeration conducted outdoors or in shed.	Operators wear rubberized gloves. Chamber stands with dump valve open for 24 hours before unloading. Regular cleaning and maintenance program. Treated material aerated for a minimum of 24 hours.	None

SOURCE: *Stevens, 1980; **Chiotakis, 1980 and Green, 1980.

TABLE C-7 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Oregon[b,c]*	Mishoe/ 45/2	10% ETO 90% CO_2	Vented through 10 ft long pipe straight above chamber.	2	Treated material hand-carried.	Two successive post-vacuums.	Fumigation conducted outdoors. Aeration conducted in polyethylene-coated structure.	Chamber door left open for 30-45 minutes before unloading chamber. Operators use self-contained breathing apparatus or gas masks and wear overalls and polyethylene gloves. Regular cleaning and maintenance program. Treated material aerated for a minimum of 24 hours.	None
Tennessee[c]**	Mishoe/ 49/2	10% ETO 90% CO_2	Vented through hose to outside of building.	1	No ventilation in fumigation room. Treated material hand-carried. Treated material aerated in same room as chamber (for a minimum of 24 hours).	One post-vacuum.	None	Chamber door left open for 30 minutes before unloading chamber. Regular cleaning program.	None

SOURCE: *Port, 1980 and Turner, 1980; **Hart, 1980.

TABLE C-7 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Virginia[c]*	Homemade/ 30/2 Homemade/ 6/4	100% ETO	Vented to area immediately outside chamber or through hose in which ETO is bubbled through an H_2SO_4 solution to form ethylene glycol.	1	Treated material hand-carried.	Two successive post-vacuums.	Fumigation and aeration conducted outdoors.	Chamber door left open for 5 minutes (with interior fan in operation) before unloading. Treated material, which is on a pallet, is pulled from the chamber by rope attached to the pallet. Treated material aerated for 48 hours. Regular cleaning and maintenance program.	None
Washington[b,d]**	Converted ammunition chest/ Not available/6	12% ETO 88% Freon®	Gas escapes when chest door is opened.	1	Treated material hand-carried. Operator potentially exposed when opening chest after cycle completion.	None	Fumigation and aeration conducted outdoors.	Chest door left open for 4 hours (with circulation fan in operation) before unloading. Treated material aerated for 24 hours. Regular maintenance program.	None

SOURCE: *Powers, 1980; **Bach, 1980.

TABLE C-7 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators^e	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
West Virginia^c	Mickoo/ 49/Not available	10% ETO 90% CO_2	Vented through dump valve immediately outside chamber.	0^f	Treated materials hand-carried.	One post-vacuum.	Fumigation conducted outdoors.	Chamber door left open for 15-20 minutes before unloading chamber. Regular cleaning and maintenance when unit is in operation.	None

SOURCE: Cole, 1980.

TABLE C-7 (CONCLUDED)

[a] Refers to the total number of qualified ETO operators at the facility, unless otherwise indicated.

[b] State which has an experimental use permit, as described in Section 5 (c) of FIFRA.

[c] State in which ETO fumigation is restricted under the control of the state regulatory agency responsible for apiary inspection, under the procedures described in Section 24 (c) of FIFRA.

[d] Chamber is operated privately, not under the supervision of Federal or state officials.

[e] Chamber is state operated.

[f] Facility does not employ ETO chamber operator at present; therefore, fumigation program is not currently being conducted.

TABLE C-8

PRACTICES RELATIVE TO WORKER EXPOSURE AT SELECTED HIGH CONTAINMENT RESEARCH LABORATORIES IN AGRICULTURE

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators*	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
National Animal Disease Center Ames, IA.	(4) Homemade/ 0.3; 3.3; 5.3; 30/10	12% ETO 88% Freon®	Negative exhaust directly into building exhaust ducts.	3	No time delay between conclusion of sterilization cycle and removal of treated material from chamber	Two successive post-vacuums.	General work area is 4588.5 cubic feet. Mechanical area ventilation system with 10 air changes per hour. Direction of air-flow is to exhaust plenum.	Safety unit personnel who work with ETO are trained by their supervisor. Chamber valves and electrical components checked annually. Workers do not enter chamber to retrieve materials. Certain treated rubber materials, such as boots, are aerated.	None

SOURCE: Sullivan, 1980.

TABLE C-8 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Plant Disease Research Laboratory Frederick, MD.	(5) Wilmot Castle/ 3, 24, 30, 144, 220/25-30	12% ETO 88% Freon®	Steam ejector evacuators. Exhausted through vent pipes to roof.	1-2	Workers may, on occasion, enter the two largest chambers. Workers do not wear protective clothing. No regularly scheduled program of equipment inspection and maintenance.	All chambers have double doors. Chamber doors are automatically locked when internal pressure is greater than 2 lbs.	Mechanical area ventilation system. Supply air is introduced then exhausted through HEPA filters. Air is changed in all rooms at the rate of 3 times per hour. Direction of general airflow is from ETO work area to non-ETO work area.	After gas is vented and internal pressure reaches zero, wheel-lock mechanism is operated to release door seal to permit residual gas to bleed from chamber. During this period, operator is away from chamber door and in the path of fresh incoming air. After a period of time, chamber door is opened and, in most instances, the chamber is left to air out overnight before the treated materials are removed. Chamber operator trained by person in charge of building.	Chambers were recently checked with detection devices that were sensitive to leaks at a rate of 10^{-7} cc/sec. Additional data not available.

SOURCE: Irish, 1980.

TABLE C-8 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of EtO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Plum Island Animal Disease Center Greenport, NY.	AMSCO/ 36/8 AMSCO/ 4/20	12% ETO 88% Freon®	Vented to exhaust system.	1-2	Equipment repaired by engineering staff not trained in ETO use and dangers.	Two successive post-vacuums.	Chamber opened from building exterior. Aeration conducted outdoors. Single-passage airflow system. Fifteen air changes per hour. Air in building is filtered through deep-bed or HEPA filter systems and discharged through stacks located on roof.	Film on lab safety regulations shown to all new employees. Sterilization area restricted to those employees who work only in animal supply. Employees trained to check if equipment functioning properly. Operators are safety technicians. Operators wear respirators and rubber gloves.	None

SOURCE: Richmond, 1980.

TABLE C-8 (CONCLUDED)

[a] Refers to the total number of persons authorized to operate ETO sterilization equipment.

TABLE C-9

PRACTICES RELATIVE TO WORKER EXPOSURE AT
SELECTED PORTS OF ENTRY

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
Baltimore Port* Baltimore, MD.	Not applicable	10% ETO 90% CO_2	Not applicable.	4-5	Not available.	Polyethylene tarpaulin, which varies in size and may be reused 26 times before it is destroyed. Tarpaulin, when in use, is secured with sand snakes	Fumigation and aeration conducted outdoors.	Treated material handled by forklift. Warning placards and guard posted during fumigation. Gas masks available, but not worn.	None
Dover Air Force Base** Dover, DE.	Not applicable	10% ETO 90% CO_2	Not applicable.	4	Not available.	Polyethylene tarpaulin (40' x 100').	Fumigation conducted in hangar. Aeration conducted in hangar or outdoors (1/2 of hangar used for fumigation; other half used for equipment storage).	Gas mask worn while cutting and removing tarpaulin. New tarpaulin used for each fumigation. Treated material handled by forklift. Treated material aerated for a minimum of 24 hours.	None

SOURCE: *Tilley, 1980; **Jernigan, 1980.

TABLE C-9 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[a]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
McGuire Air Force Base* Ricetown, NJ.	Not applicable.	10% ETO 90% CO_2	Fan positioned under tarpaulin.	3-4	Not available.	Polyethylene tarpaulin used for fumigation.	Fumigation conducted in maintenance garage (with floor to ceiling doors). Aeration conducted in garage or outdoors.	New tarpaulin used for each fumigation. Tarpaulin glued to floor during fumigation. Self-contained breathing apparatus worn while cutting and removing tarpaulin. ETO evacuated by fans located under tarpaulin. Treated material aerated for 24 hours. Treated material transported by forklift.	Fumiscope used to monitor concentration of ETO in garage after removal of tarpaulin.
New Orleans Port** New Orleans, LA.	Not applicable.	10% ETO 90% CO_2	Fans.	4-5	Not available.	Polyethylene tarpaulin used for fumigation.	Fumigation and aeration conducted outdoors.	Tarpaulin may be used for up to 4 fumigations. At end of cycle, wet sand is removed from borders of tarpaulin (starting from downwind side) and tarpaulin is lifted. Fans are operated for approximately 3 hours before cargo is moved. Gas masks worn during removal of tarpaulin. Treated material transported by forklift.	None

SOURCE: *Gervasoni, 1980; **Bourgeois, 1980.

TABLE C-5 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators*	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
New Orleans Port* New Orleans, LA.	Not applicable.	10% ETO 90% CO_2	Fans.	4-5	Not available.	Polyethylene tarpaulin used for fumigation.	Fumigation and aeration conducted outdoors.	Tarpaulin used for up to 2 fumigations. Warning placards and guards posted during fumigation. Gas masks made available to operators. At conclusion of cycle, the downwind corner of tarpaulin is lifted, 6 to 8 fans ventilate the load under the tarp for 15 minutes, and then the tarpaulin is removed. Treated material transported by forklift.	None
New Orleans Port** New Orleans, LA.	Not applicable.	10% ETO 90% CO_2	Not applicable.	4-5	Not available.	Polyethylene or double-ply, laminated polyethylene tarpaulin used.	Fumigation and aeration conducted outdoors.	Polyethylene tarp used for up to 2 fumigations. Double-ply laminated polyethylene tarpaulin used for up to 5 fumigations. Treated material transported by forklift. Gas masks made available to operators. One downwind corner of tarpaulin lifted for 30 minute period. Then other downwind corner lifted for another 30 minutes. Finally, tarpaulin is removed.	None

SOURCE: *Iebill, 1980; **Wilson, 1980.

TABLE C-9 (CONTINUED)

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators^a	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO
	Equipment Manufacturer/ Size (ft^3)/ Age (years)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design	Work Practices	
New York Port* New York, NY.	Not applicable.	10% ETO 90% CO_2	Fans.	4-5	Not available.	Polyethylene tarpaulin.	Fumigation and aeration performed outdoors or in abandoned warehouse.	New tarpaulin used for each fumigation. Self-contained breathing apparatus available to workers. Warning placards and guards posted during fumigation. Treated material transported by forklift. One of two methods used to evacuate gas and aerate material: Fan attached to hose leading out of warehouse. When reading of zero received on Fumiscope, tarpaulin removed. Opposite ends of tarpaulin are lifted and fans, blowing in the same direction. are placed at each end. This creates a draft which continues for 15 minutes. Then the tarpaulin is removed.	None
New York Port** New York, NY.	Not applicable.	10% ETO 90% CO_2	Not applicable.	Not available	Not available.	Polyethylene tarpaulin.	Fumigation performed in empty warehouse.	Not available.	Not available.

SOURCE: *Arch, 1980 and Arch, 1980a; **Kolbe, 1980.

TABLE C-9 (CONCLUDED)

[a] Refers to the total number of persons authorized to operate ETO fumigation equipment.

TABLE C-10

PRACTICES RELATIVE TO WORKER EXPOSURE AT
SPICE INDUSTRY SITES

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{a}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{a}
	Size of Sterilizer (ft^{3})	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{a,c}	Work Practices^{a}	
Site A	384	100% ETO	Vented to sewer.	2	Operators unload sterilizer immediately upon opening of chamber door. Treated materials not aerated in aerator or specially designed aeration room.	Two post-vacuums.	Sterilizer located in separate room (12' x 30' x 15') with 1400 cfm^{d} mechanical area ventilation (fans).	Access to ETO work area is restricted to ETO sterilization workers. Pallets containing fumigated materials are removed from chamber by lift truck. Vacuum pumps and process cycle controller inspected daily.	In 1970, personnel from division of industrial safety and the Orange County Division of Environmental Health performed tests to check ETO levels in and about the chamber. Additional data were not available.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site B	(2) 255	12% ETO 88% Freon®	Vented to sewer drain and to atmosphere.	1	Operator must enter chamber to unload treated material. Treated materials (in containers) are manually unloaded from chamber to a pallet.	One post-vacuum. Vacuum pump draws ETO to water scrubber. ETO solution drained to sewer and inert gas vented to atmosphere.	Sterilizer located in open space (40' x 40') away from general work area (with natural, open-space ventilation). ETO cylinders are isolated from sterilizer. Sterilized product stored in open air staging area for short period of time prior to delivery.	Access to ETO work area is restricted to authorized personnel. At completion of sterilization cycle, chamber door is left opened for 1 hour before treated materials are removed. Pallets containing ETO-treated materials transferred to open air staging area by forklift. Operator receives four weeks of actual in-plant training regarding safety, handling and use of ETO cylinders, and operation of sterilization chambers. Chamber door, ETO isolation valves, air purging, and exhaust system are inspected daily.	None

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site C	312 (manufactured by Vacudyne-Altair)	12% ETO 88% Freon®	Vented to outside atmosphere.	1-4	At completion of cycle, chamber remains closed for 4 to 12 hours before door is opened. Operators must enter chamber to unload treated materials. Small treated packages removed from chamber by hand and left out near aerator for 1 to 2 days.	Two post-vacuums. Control panel contains emergency controls and safety devices. Pressing of Emergency Stop button aborts process cycle. Warning alarm system which sounds when pressure falls below normal operating levels indicating possible leak to chamber.	Sterilizer located in warehouse area (60'x60'x20') away from production area. Mechanical area ventilation with rate of air exchange of 1200 cfm.[d]	Access to ETO work area restricted to sterilizer operators and supervisor. Chamber door is opened for 2 hours before treated materials are removed. Treated materials on pallets removed by forklift truck. Operators wear goggles, gloves, respirator (organic vapor and gas cartridge approved by MESA and NIOSH) supplied by Norton Safety Products. Facility also provides protective clothing. Operating procedures, including safety precautions, provided by Vacudyne. Qualified engineer monitors procedures regularly and trains operators. Operator cannot overlook or skip any steps in the procedure without the approval of the plant supervisor or plant engineer. Workers not following proper procedure are subject to disciplinary action. Qualified engineer inspects door gaskets for cuts and tears. Other malfunctions of unit are routinely repaired. Automatic valves are checked and surfaces are scraped and repainted semiannually.	None

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{a}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{a}
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{a,c}	Work Practices^{a}	
Site D	666	100% ETO	Vented to sewer drain.	1-4	Operators must enter chamber to unload treated materials. Quarantine area for treated materials not equipped with ventilation system.	None specified	Sterilizer located in work area (60'x25'x17 1/4") with mechanical area ventilation and rate of air exchange of 4333 cfm.^{d} Direction of air flow is from non-ETO area to ETO work area to outside atmosphere. Treated materials are stored in designated quarantine area of general warehouse for 3 days.	At completion of cycle, chamber door is cracked open for 15 minutes (with vacuum pump operating). Treated materials are not removed until an additional 30 minute period has passed. Operators receive an 8 to 12 week initial training program and periodic reviews in quarterly training sessions. These sessions are held biweekly on standard operating procedures, good manufacturing processes, and safety. Instruments are checked and calibrated quarterly by outside firm. Checked monthly by internal plant engineer.	Monitoring being conducted at present (September 1980) using Mine Safety Appliance Co. Personnel Portable pump and Wilks-Miran-101 Vapor Analyzer. Additional data were not available.
	1329	100% ETO	Vented to sewer drain.						

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft³)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site E	533	12% ETO 88% Freon®	Vented to atmosphere and to drain.	2	Access to ETO work area is not restricted. Treated materials are removed from chamber immediately after opening of chamber door. Treated spice products are stored in same area as the sterilizer.	One post vacuum. Three air-washes. Liquid/gas separator.	Sterilizer located in general storage area (120'x120'x12') with mechanical area ventilation system and rate of air exchange of 3100 cfm.[d] Direction of airflow is through storage area to outside atmosphere.	Operators have received specific instructions on operation of the sterilizer and hazards associated with its use. Sterilizer operators report any deviations from normal operating procedures to supervisor. Monthly inspection and maintenance program performed, including inspection of door gasket, door securing handles, vacuum pump seals, and other parts.	Monitoring performed using Miran 103 gas analyzer on spot-check basis. Facility reports that ETO levels are "well below" OSHA standard of 50 ppm.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[f]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site F	533	12% ETO 88% Freon®	Vented to outside atmosphere.	1	Access to ETO work area is unrestricted.	Two post vacuums. Chamber equipped with electrical interlocks to prevent opening of chamber door prior to completion of cycle.	ETO work area (20' x 30') located in 72,000 ft^3 warehouse with mechanical area ventilation system with rate of air exchange of 28,000 cfm.[d]	At completion of sterilization cycle, chamber door is opened for 45 minutes before treated materials are removed. Treated materials are retrieved from chamber using a hook and chain system over roller conveyors. Treated materials are transported to aeration area using a forklift. Operators and other workers attend training sessions on ETO sterilization followed by periodic review and update of safety and handling procedures. Current inspection and maintenance includes weekly equipment inspection and daily check procedures. Maintenance is also scheduled based on check required.	Monitoring of environmental levels has not been performed; however, residual ETO in products sterilized is monitored.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Steril[illegible] (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site G	360	100% ETO	Vented to sewer drain.	2	There is no time delay between opening of chamber door and retrieval of treated materials.	Two air purges. When chamber doors are locked, mechanical fan is automatically placed into operation (location of fan was not specified).	Sterilizer located in separate room (32' x 20' x 25') with mechanical area ventilation system and air exchange rate of 1,500 cfm.[d] Aeration area covered by curtain doors leading to loading dock (with natural area ventilation).	Access to ETO sterilization room is limited to supervisor of sterilization operations, chamber operator, and other authorized supervisory personnel. Treated materials loaded onto pallets. At completion of cycle, treated materials on pallets are rolled out of chamber and transferred (using forklift) to area near loading dock. Operators receive thorough indoctrination on health and fire hazards of ETO. Operators are instructed that in the event of chamber malfunction, treatment is to be discontinued and management is to be notified immediately. Cursory onsite inspection every time the chamber is to be operated. Continuous monitoring of control panel recorder.	Monitoring of environmental levels has not been performed; however, residual ETO in products sterilized is monitored.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site H	330	12% ETO 88% Freon®	Vented to outside atmosphere.	1-4	Not Available.	One air flush.	Sterilizer located in work area (22' x 30' x 16') in plant with mechanical area ventilation system and 10 air changes per hour.	Access to ETO work area is limited to ETO sterilization workers. Treated material removed from chamber using a forklift and transferred to designated (and ventilated) aeration area. Operators wear goggles and respirators in ETO work area. Operators receive 3 month training, and written sterilization procedures are posted on wall near sterilizer. Chamber is checked on a regular schedule for equipment malfunction.	None

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site 1	(2)800	100% ETO	Vented to sewer.	2-4	Not specified.	Three air purges. Chamber equipped with alarm monitoring system (additional data not reported) and interlocks to prevent opening of door prior to completion of cycle.	Sterilizers located in areas that measure 30' x 24' x 15', 40' x 30' x 24', 40' x 30' x 20', and 40' x 30' x 18', respectively. ETO work area for first 4 chambers have mechanical area ventilation system with air exchange rate of 5000 cfm;[d] other ETO area has passive area ventilation. Direction of air flow is from ETO area to non-ETO areas at all 4 ETO work areas.	Access to ETO work area is restricted to authorized personnel. At completion of cycle, chamber door is opened for 10 minutes prior to unloading treated goods. Pallets moved to front of chamber using cables and transferred to open area for aeration using fork truck. Protective clothing is available for the workers. Formalized training program using posted procedures. Sterilization equipment inspected weekly by maintenance personnel.	Monitoring has been conducted. Additional data were not available.
	1400	100% ETO	Vented to sewer.						
	1600	100% ETO	Vented to sewer.						
	1100	100% ETO	Vented to sewer.						

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site J	280	12% ETO 88% Freon®	Vented to atmosphere.	1-4	Not available.	Two air washes.	Sterilizer located in warehouse (90' x 18' x 30') equipped with mechanical area ventilation system (exhaust fan) and rate of air exchange of 100 cfm.[d] Direction of airflow is from non-ETO work area towards ETO area. Exhaust vents located beneath chamber door. Aeration room ventilated with exhaust fan.	Access to ETO sterilization area is restricted to authorized personnel. At end of cycle, chamber door is opened for 20 minutes (with exhaust fan operating) before treated materials are removed. Operators wear cloth work gloves or vinyl disposable gloves. Each worker is trained in proper sterilization procedures. Facility has written procedures manual. Entire chamber mechanism (gaskets, seals, joints, exhaust, etc.) is periodically checked for defects.	None

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site K	363	12% ETO 88% Freon®	Vented to sewer drain.	2	Workers must enter chamber to unload treated materials.	Multiple post-vacuums. Two air washes.	Sterilizer located in shipping room (90' x 70' x 11') with passive area ventilation (cross ventilation from dock door and windows near chamber area). Direction of airflow is from non-ETO work area towards ETO area.	Access to ETO area is restricted to authorized personnel. At completion of cycle, chamber door is opened for 20 minutes prior to unloading of treated materials. Operators supplied with cloth work gloves or vinyl disposable gloves. Operators trained in proper sterilization procedures and follow procedure manual. Regularly scheduled program of equipment maintenance is performed.	None

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site L	921	12% ETO 88% Freon®	Vented to outside atmosphere and sewer drain.	1-4	Access to sterilizer and storage warehouse areas is not to ETO sterilizer operators; however, there is a "minimum" of employee traffic in sterilizer area. Lift truck operator must enter chamber to retrieve treated materials.	Three air washes.	Sterilizer located in warehouse (200' x 50' x 40') with mechanical area ventilation systems (exhaust fans) and two air changes per hour. Direction of air flow is from ETO work area to non-ETO work areas. Exhaust fan in roof of aeration area which operates continuously, drawing air from this area and exhausting it to outside atmosphere.	At completion of cycle, chamber door is opened approximately 1 foot for 30 minutes. Treated materials are transferred from sterilizer to designated area adjacent to sterilizer (for a 48 hour quarantine period) using a lift truck. Self-contained portable air-pack is available to operator for emergency situations. Sterilizer operators are trained by Quality Control Department on proper sterilization procedures and monitoring techniques. Quality Control Manager and Plant Sanitarian are licensed by state in fumigation techniques. Sterilizer is monitored daily by operators; malfunctions are reported immediately to Engineering and Maintenance Departments. Sterilization charts are monitored by Quality Control Department on daily basis for proper gassing, sterilization time, and chamber evacuation.	ETO levels were monitored immediately after opening door and four minutes after door opened. Samples were collected using Bendix BDX-44 sampling pump and charcoal collection tubes and analyzed on gas chromatograph (following NIOSH Procedure S286). Chamber is monitored daily to assure compliance with OSHA standards for occupational exposure to ETO. In response to data obtained from monitoring, delay of ½ hour between opening of chamber door and unloading chamber was instituted in procedures. Honeywell Gas/Vapor Detector for Freon 12, equipped with visual and audible alarm system and located adjacent to chamber, used for continuous monitoring of gas levels in the workplace.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft³)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site H	650	12% ETO 88% Freon®	Vented to sewer drain and outside atmosphere.	1-4	Access to sterilizer and aeration area is not restricted to sterilizer operators; however, sterilizer located in an area where there is a "minimum" of employee traffic. Operator must enter chamber to retrieve treated materials.	Three air washes. Door operating switch is remote-controlled.	Sterilizer located in warehouse (14' x 28' x 25') with mechanical area ventilation (wall exhaust fan located behind chamber continuously draws air away from chamber and to outside atmosphere) with 1 air change per hour. Direction of airflow is towards ETO area from non-ETO area.	At end of cycle, chamber door is opened mechanically by remote-control (operator is not at doorway when chamber door is opened). Treated material is transferred from sterilizer to designated quarantine area using lift truck. Organic vapor respirators are provided to operators. Quality Assurance Manager instructs operating personnel and foremen in sterilization procedures. Complete operating instructions are posted on chamber near control panel. Plant maintenance personnel perform monthly preventive maintenance check of all mechanical components.	ETO levels were monitored immediately after opening of chamber door. Samples were collected using Bendix BDX-44 sampling pump and charcoal collection tubes and analyzed on gas chromatograph (following NIOSH Procedure S286). Survey of sterilization operation, equipment and storage areas was made using infrared gas analyzer. Two monitorings reported that ETO concentrations were in compliance with OSHA standards for occupational exposure to ETO (over an 8 hour TWA). In response to data obtained from monitoring, 15 minute post-sterilization air wash with chamber door open was incorporated into automatic sterilization cycle. Facility reported that inclusion of air wash has "assured" minimum

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site M (Concluded)									gas exposure levels, but did not provide additional data. Honeywell Gas/Vapor Detector for Freon 12, equipped with visual and audible alarm system and located adjacent to chamber, used for continuous monitoring of gas levels in the workplace.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site N	281	12% ETO 88% Freon®	Vented to outside atmosphere.	1	Operator must enter chamber for 2-3 minutes to retrieve treated materials.	Two air washes.	Sterilizer located in storage room (60' x 40' x 15') with mechanical area ventilation (fans) with air movements of 3,000 cfm.[d] Direction of airflow is from non-ETO area towards ETO area.	Access to ETO work area is restricted to sterilizer operator. At end of cycle, chamber door is opened for 20 minutes before unloading chamber. Operator wears work gloves or vinyl disposable gloves. Operators trained in sterilization procedures. Written procedure manual available. Door seal check and overall maintenance check are performed periodically.	None

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site O	395	100% ETO	Vented to sewer drain.	2	Not available.	Two post-vacuums. Automatic shut-off of ETO injection if chamber pressure is too high.	Sterilizer located in area (30' x 12' x 22') with mechanical area ventilation with 30 air changes per hour. Direction of airflow is towards ETO area from non-ETO area. Storage (aeration) area vented to outside atmosphere.	Access to ETO work area is restricted to two sterilizer operators. At end of cycle, chamber door is opened for 10 minutes prior to unloading of chamber. Treated materials are transported to storage area for aeration. Operators receive intensive verbal training and written procedures. ETO volatilizer and evacuation system are checked routinely and maintenance is performed regularly.	Monitoring has been performed using portable Linde ETO analyzer. Facility reported that corrective actions have been taken in response to data obtained from monitoring and that ETO levels have been reduced to "well below" OSHA standard for occupational exposure to ETO.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site P	249	12% ETO 88% Freon®	Not reported.	3	Access to sterilizer room is not restricted; however, facility reports that access is limited due to its separation from other operations. Workers must enter chamber to hook tow chain to palletad goods.	Three post-vacuums.	Sterilizer located in separate room (52'6" x 36'6" x 22') with mechanical area ventilation (rotoclone exhaust fan) with air movements of 8500 cfm.[d]	Particle respirator worn in ETO sterilization area. Operators receive on-the-job training from a previously trained operator. Training audited by Quality Control and Engineering Departments. Recorder charts for all cycles are examined by Quality Control to determine if abnormalities have occurred during treatment process. Complete records and recorder charts are maintained by Manufacturing Department and filled by Quality Control Department.	Employee exposure to ETO monitored following NIOSH analytical method S286. Eight hour TWA for sterilizer operator was recorded at 1.6 ppm. Additional data were not available.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{a}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{a}
	Size of Sterilizer (ft^{3})	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{a,c}	Work Practices^{a}	
Site Q	120	12% ETO 88% Freon®	Vented to outside atmosphere.	1	Not available.	Three post-vacuums.	Sterilizer located in warehouse storage area (40' x 22' x 27') with passive area ventilation.	Access to ETO work area restricted to operator. Treated materials are removed from sterilizer by fork truck. Supervisor instructs operator according to standard written operating procedures. Regular maintenance on vacuum pump.	Employee exposure to ETO monitored following NIOSH analytical method S286. Eight hour TWA for sterilizer operator was recorded at 0.29 ppm. Additional data were not available.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site B	1400[e]	100% ETO	Vented to sewer drain.	2	Fork truck (and operator) must enter chamber to remove treated materials.	Three air purges.	Chamber area measures 40' x 30' x 24' and has mechanical area ventilation with air movements of 5,000 cfm.[d] Direction of airflow is from non-ETO area to ETO work area. Exhaust vent located above chamber. Alarm monitoring system; additional data not provided.	Access to ETO work area is restricted to ETO fumigation workers. At completion of cycle, chamber door is opened for 10 minutes before chamber is unloaded. Treated materials transferred from sterilizer to open aeration area using fork truck. Operators wear respirators when opening chamber door. Operators undergo formalized training program using posted procedures. Maintenance Department inspects chamber weekly.	Monitoring has been performed. Additional data were not available.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[a,c]	Work Practices[a]	
Site 8	1600[e]	100% ETO	Vented to sewer and outside atmosphere.	2	Not available.	Three air purges. Interlocks.	Chamber room measures 40' x 30' x 20' and has mechanical area ventilation with air movements of 5,000 cfm.[d] Direction of airflow is from non-ETO area to ETO area. Alarm monitoring system; additional data not provided. Exhaust vent located above chamber. Dislocated controls; additional data not available.	Access to ETO chamber area is restricted authorized personnel. At completion of cycle, chamber door is opened for 10 minutes before chamber is unloaded. Cables used to drag pallets to front of sterilizer; pallets are then transferred to open aeration area using forklift. Operators wear respirators when chamber door opened. Operators undergo formalized training program using posted procedures. Maintenance personnel inspect chamber weekly.	Monitoring has been performed. Additional data were not available.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators^{a,b}	Potential Exposure Situations^{a}	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO^{a}
	Size of Sterilizer (ft^{3})	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design^{a,c}	Work Practices^{a}	
Site T	1100^{e}	100% ETO	Vented to sewer drain and to outside atmosphere.	2	Not available.	Three air purges Interlocks.	Chamber area measures 40' x 30' x 18' and has passive area ventilation (outside). Direction of airflow is from non-ETO area to ETO area. Alarm monitoring system; additional data not provided. Exhaust vent located above chamber. Dislocated controls; additional data not available.	Access to ETO work area restricted to authorized personnel. At completion of cycle, chamber door is opened for 10 minutes prior to unloading of chamber. Cables used to drag pallets to front of sterilizer; pallets are transferred to open aeration area using forklift. Operators wear respirators when chamber door is opened. Goggles and gloves are available for use at discretion of operator. Operators undergo formalized training program using posted procedures. Maintenance personnel inspect chamber weekly.	Monitoring has been performed. Additional data were not available.

TABLE C-10 (CONTINUED)

Facility	Sterilization/Fumigation Equipment			Total Number of Operators[a,b]	Potential Exposure Situations[a]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[a]
	Size of Sterilizer (ft^3)	Sterilant Used	Gas Removal System			Equipment Design	Workplace Design[b,c]	Work Practices[a]	
Site U	(2)750 1320	100% ETO	Vented to sewer drain.	2	Not available.	One post-vacuum.	Chamber room (42' x 32' x 10') equipped with mechanical area ventilation with 4 air changes per hour. Direction of air-flow is from non-ETO work areas to ETO work area. Exhaust system in storage (aeration) area.	Access to ETO fumigation area is restricted to authorized personnel. At completion of cycle, chamber door is partially opened for 30 minutes before chamber is unloaded. Pallets in rear of chamber pulled forward using tow bar. Treated materials are transferred from chamber room to storage area using a fork truck. Operators wear partial face respirators during removal of pallets from chamber if entry into chamber is required. Operators trained by department supervisor using written procedures document during on-the-job instruction (covering safety and sterilization procedures). Supervisor makes final check of system before every sterilization cycle. Equipment inspected monthly by company in accordance with written plant procedure. In addition, company's insurance carrier inspects equipment 4 times annually.	Chamber room and aeration area monitored using Wilks-Miran 101 analyzer. First monitoring test were performed using Linde Atmospheric Monitor. In response to data obtained from monitoring, ventilation was increased, 30 minute delay between opening and unloading of chamber was instituted, and use of respirator if worker must enter chamber was required. Facility reported that changes did decrease ETO levels in plant and that employee exposure to ETO (as an 8 hour TWA) has been recorded at 12.6 ppm and 17.4 ppm.

TABLE C-10 (CONCLUDED)

[a] Data in this column apply to all ETO sterilizers, sterilizer operators, or ETO work areas at this facility.

[b] Refers to the total number of persons authorized to operate ETO sterilization equipment at this facility.

[c] Where indicated, the dimensions of ETO work areas represent length x width x height.

[d] Refers to cubic feet per minute.

[e] Size of sterilizer is measured in square feet (ft^2).

TABLE C-11

PRACTICES RELATIVE TO WORKER EXPOSURE AT COSMETICS INDUSTRY SITES[a]

Facility/ Location	Sterilization/Fumigation Equipment			Total Number of Operators[c]	Potential Exposure Situations[b]	Control Measures Implemented			Monitoring of Workplace for Residual Levels of ETO[b]
	Size of Sterilizer (ft³)	Sterilant Used[b]	Gas Removal System[b]			Equipment Design[b]	Workplace Design[b-d]	Work Practices[b]	
Micro-Biotrol Bound Brook, NJ.	250 375 442 509 659 662 663	100% ETO	Via vacuum pumps to water separator and thence to sewer. Separator also vented through roof stack.	11	Operators must enter chamber to retrieve treated materials.	One or more post-vacuums drawn to evacuate ETO from free space of chamber. One vacuum is typically employed; however, a second full vacuum is drawn prior to opening of chamber if one hour or more has elapsed since conclusion of cycle. Circulation system to facilitate even distribution of heated ETO/air gas mixture throughout chamber (particularly in rear of chamber where air circulation may normally be limited) is built into chamber and operated during unloading.	Mechanical area ventilation (fans). Direction of air-flow is towards ETO area from non-ETO area. Fans located above chambers which direct air-flow away from worker and facilitate dispersion of ETO once it has escaped from chamber. Storage room (ventilation/aeration area) equipped with air circulation systems in which fresh air is introduced at ceiling level and vented at floor level.	Access to ETO sterilization area restricted to authorized personnel. At end of cycle operators loosen hand wheels on chamber door. There is a time delay of at least five minutes while operator brings over and puts in place ramp, readies identification stamp, and then stamps stickers with lot number. Materials are removed from chamber by using construction battery powered transports or hand pallet mover. Pallets are then stored in specially designated warehouse area. Operators spend 8 hours per shift on ETO gas treatment and are responsible for gas processing of materials. Three month in-house training program for new employees on ETO procedures, including instruction in hazard identification and procedures to be followed in case of emergency. Equipment serviced by in-house personnel twice annually. Have instituted system of record-keeping for inspection and maintenance.	Monitoring has been performed using gas chromatography and Wilks-Miran 101 Gas Analyzer. Based on this monitoring, Micro-Biotrol reports that workers at its facilities are exposed to less than 50 ppm as an 8 hour time weighted average. Additional data not made available.
Chicago, IL.	239 (3) 280 360 (2) 660 668			4					
Levittown, PA.	(3) 660			2					
Los Angeles, CA.	239 (2) 280 638 664 717 736			8					
Smyrna, GA.	(3) 436 443			2					

TABLE C-11 (CONCLUDED)

[a] Micro-Biotrol, a contract sterilizer, fumigates 80 to 84 percent of the cosmetic raw materials and 100 percent of the hardware items used by the cosmetics industry. In addition to cosmetics, Micro-Biotrol sterilizes spices, medical products, and dairy packaging products.

[b] Data in this column applies to each of the five sites listed.

[c] Refers to the total number of persons authorized to operate ETO sterilization/fumigation equipment at this facility.

[d] The dimensions (length x width x height) of the ETO work area and the rate of air exchanges or movements at the five Micro-Biotrol facilities are:

Bound Brook: 87' x 45' x 21', 5000 cubic feet per minute (cfm);
Chicago: 70' x 32' x 11½' and 52' x 28' x 13', 6500 cfm in 70' long room and 3000 cfm in 52' long room
Levittown: 40' x 40' x 20', 3500 cfm;
Los Angeles: 78½' x 51½' x 20', 9 air changes per hour;
Smyrna: 38' x 27' x 28', 3500 cfm.

SOURCE: Alguire, 1979; 1980; Yeung, 1980.

Department Approval: Bernard B. Fuller

MITRE Project Approval: